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The purpose of this research was to identify factors influencing African-American women's (AAW) decisions to participate in breast cancer prevention research (BCPR). The theoretical basis included the Health Belief Model (HBM), Theory of Reasoned Action (TRA) and the Transtheoretical Model (stage of behavior change). A combined qualitative (focus groups) and quantitative (mail survey) approach was used. A convenience sample of 45 AAW participated in eight focus group discussions to identify beliefs and attitudes about breast cancer and research participation. Findings were used to develop a survey questionnaire which was tested for validity and reliability. A mail survey involving 10,000 women in the Los Angeles area, with oversampling of AAW, was conducted in Spring, 1996. The survey response rate was 5.2% (N=512, 311 AAW) which is similar to the response rate for mass mailing recruitment strategies used for prevention trials. Items explored beliefs and attitudes about breast cancer, medical research, preferred type of prevention behavior and interest in BCPR participation. Using bivariate and multivariate techniques, important factors, in order of importance, influencing AAW's BCPR participation behavior included: benefits and barriers of research participation, perceived seriousness of breast cancer, social norm, behavioral control, insurance status, education, referent influence, and prior research participation. Findings offer possibilities for tailoring recruitment strategies to meet the needs and concerns of AAW.

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Linda Lillegard RN, BSN 8/29/97

PI - Signature Date

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Introduction:

For at least the last 30 years there has been a disparity in the rate of breast cancer survival between African-American and White women (1). Despite the recent advances in prevention, diagnosis, and treatment of cancer, unfavorable cancer rates have persisted in African-Americans. According to the most recent data, the 5-year relative survival rate for breast cancer among African-American women is 69%, compared to a rate of 84% among white women (2). To explore this disparity, the National Cancer Institute's Black/White Cancer Survival Study Group examined the relationship between sociodemographic, behavioral, clinical stage at diagnosis, and health care access factors to the race-stage difference. Results revealed no single factor or group of factors could explain more than 50% of the disparity suggesting further research is needed to explain this poor outcome (3).

The effect of breast cancer prevention is currently being evaluated to determine the potential to reverse the disproportionate breast cancer morbidity and mortality in African-American women. Nationally funded research trials aimed at breast cancer prevention in women at high risk are now underway: the National Surgical Adjuvant Breast and Bowel Project (NSABP) Breast Cancer Prevention Trial (BCPT) is evaluating the effect of tamoxifen as breast cancer prevention; and the Women's Health Initiative (WHI) will assess, as one component, the effect of dietary modification (low-fat diet) on breast cancer incidence. The BCPT prospectively recognized the need to actively recruit ethnic minority populations to allow results to be generalized to the entire United States population by requiring a minority recruitment plan to be submitted with each application. However, even when prospective strategies to include minority populations were proposed, the accrual rate of minority women has been less than the representative distribution of the United States population (4).

The Women's Health Trial Feasibility Study, also recognizing the need to rectify this problem, targeted accrual of minority women at three centers across the country to test methods to enable minority women to change their eating habits as a prelude to the WHI. The few centers involved limited opportunities for participation by women outside these geographic areas. Recruitment of adequate numbers of minority women to national breast cancer prevention trials has been problematic, thus jeopardizing the generalizability of findings from key breast cancer prevention trials to the African American population.

To ensure adequate representation, African American women would have needed to comprise 12% of the total study population for each trial. The ineffectiveness of prospectively designed recruitment strategies provides evidence for the need to address issues related to African-American women's participation in breast cancer prevention research (BCPR). There is a need to develop recruitment strategies based on an adequate and accurate understanding of African-American women's perceptions, beliefs and attitudes regarding breast cancer prevention and research participation so that African-American women throughout this county may participate and benefit.

The purpose of this study was to identify and explore African-American women's attitudes, perceptions and beliefs about breast cancer and participation in BCPR. The objectives were to: 1) determine the culturally salient perceptions, attitudes and beliefs of African-American women regarding breast cancer and research participation using focus group techniques; 2) design a culturally sensitive, theoretically based survey instrument to identify factors influencing decisions to participate in BCPR; 3) determine the psychometric properties of the instrument via expert judge panel review, pretesting by the focus group participants, and pilot testing in a convenience sample of 40 representative African-American women; and 4) identify the relative strength and interaction of factors influencing decisions to participate in breast cancer prevention research trials via a descriptive mail survey.

Research questions addressed included: 1) what are the common health beliefs regarding breast cancer among African-American women?; 2) what are the perceptions, attitudes and beliefs of African-American women regarding medical research and participation in research trials?; 3) what effect do perceptions, attitudes, and beliefs have on the decision making process and expressed interest in participating in BCPR?; and 4) what cognitive, social and environmental factors influence African-American women's decisions to participate in BCPR?

Background:

Few studies have examined the perceptions, beliefs and attitudes of African-Americans regarding medical research participation. Assumptions regarding factors influencing African-American's participation in research have been identified as: 1) hesitancy to participate in research due to ethical issues; 2) health professional's lack of information regarding cancer trials; 3) lack of knowledge regarding cancer prevention and opportunities for participation in research; 4) unwillingness to consider investigational trials as opportunities for participation by healthy individuals; 5) historical barriers regarding research participation (racial issues); 6) inconvenience (time, transportation, cost), fear/anxiety regarding side effects and procedures; and 7) family influences (5,6,7).

A study by Millon-Underwood and colleagues reported findings from a descriptive survey of 220 African-Americans in the midwest (6). Results indicated that the main factors influencing research participation were the perceived efficacy of the investigational program and misconceptions regarding opportunities for research participation limited only to those with the disease. Swanson and Ward (1995) identified four general categories of barriers and promoters of research participation from an extensive review of the literature (8). Barriers included access, structural factors, sociocultural factors including awareness of the Tuskeegee Syphilis study leading to widespread distrust of medical research by African Americans, and beliefs of researchers, which when taken together, limit access of researchers to eligible populations of African Americans. Roberson (1994) reported results from a recent telephone survey involving 31 respondents (8 African American, 10 Hispanic, and 10 Native American Indian respondents) regarding participation in clinical trials (9). Similar findings among all three cultural groups included a "mistrust" of white people and feeling of being treated like a guinea pig. Identified benefits of clinical trial participation included "helping to find a cure", way to help others, means to "assist with medical coverage (health insurance), and educate families. Barriers to participation identified by African Americans included fear, lack of information about ongoing research, and feeling of being treated like guinea pigs. Thoughts about who should participate in clinical trials included "real sick" patients.

Robinson and colleagues (1996) conducted focus groups to determine attitudes of African American men regarding prostate cancer clinical trials (10). Many participants indicated that they would be more likely to participate in clinical trials if they were encouraged to do so by a physician who was viewed as competent and compassionate. Barriers to participation included concerns about drug toxicity, medical exprimentation, and distrust of the medical establishment.

Preliminary Research:

Prior to the conduct of this research, a preliminary pilot study was conducted using a theoretically based semi-structured interview to identify attitudes and beliefs of minority women (N=30) regarding breast cancer prevention (12). Findings revealed a lack of understanding among African-American women (N=10) regarding primary and secondary prevention behaviors. Although participants associated diet with cancer prevention and health maintenance, women did not associate a low-fat diet with breast cancer prevention. When given information about current studies evaluating breast cancer prevention, diet vs. pill (tamoxifen), 80% of African-American women identified a preference for making dietary changes due to the "natural" approach.

A process evaluation examining African-American women's reasons for refusal to participate in the NSABP BCPT revealed a lack of belief in susceptibility to breast cancer, concern about the impact of the "study medicine" on their current medical condition and therapy, and concerns about side effects (15). A "mock recruitment" identifying the breast cancer patient as an index for identifying high risk family members for potential participation in the NSABP BCPT predicted potential recruitment difficulties (12). Barriers precluding contact of potential participants included no current phone number and lack of family awareness of the diagnosis.

These preliminary studies provided the basis for the research completed in this project specifically identifying a need to: 1) further explore the perceptions, attitudes and beliefs of African-American women regarding breast cancer, breast cancer prevention, and research participation to develop tailored communication messages to alter misconceptions and enhance recruitment to breast cancer research trials; 2) identify the factors influencing potential acceptance of breast cancer prevention behavior by African-American women given the current lack of understanding regarding the difference between prevention and early detection; 3) further explore African-American women's preference for type of BCPR participation (diet vs. pill); and 4) identify alternate strategies for recruitment of African American Women to BCPR trials.

Theoretical Framework

Using the Health Belief Model (HBM), Theory of Reasoned Action/Planned Behavior (TRA), Transtheoretical Model and related literature organized according to the PRECEDE Health Education Planning Framework, the study focused on the cognitive, social and environmental factors that theoretically may influence research participation (14). The HBM has been widely used to explain health related behavior including breast self-exam and mammography screening behavior (15). The model components having the most consistent impact on these behaviors include perceived susceptibility and seriousness, benefits/barriers, knowledge, and general health motivation. The TRA suggests that behavioral control, i.e. confidence in ability to perform the behavior is an important predictor of health behavior. The TRA proposes intention is central to understanding behavior. Intentions predict behavior and mediate all other variables that might impact behavior. The determinants of intention are expectancy values concerning personal attitudes and beliefs about the behavior and influence of the social environment, and behavioral control. A major advantage of this theory is its empirical tie to the individual's own evaluations requiring an initial exploration of salient beliefs, relevant consequences and norm beliefs among individuals in the target population. Guidelines are specified for operationalizing these constructs and developing measurement instruments grounded in the target population for the topic of interest.

Additional variables identified in the literature as potentially impacting research participation include: medical history, environmental factors (cost, time, transportation), social desirability, religiousness, racism, and demographic characteristics (5,16,17).

The combined framework suggests that communication messages and interventions tailored to the social and cultural norms of the target population related to predisposing, enabling and reinforcing factors would have the greatest chance for impacting attitudes and beliefs, behavior control and social norm and consequently intention, and BCPR participation behavior (Appendix A - Diagram 1.)

Body - Research Design and Methods:

A combined qualitative and quantitative approach was used involving focus group discussions, questionnaire development, and a mail survey.

Focus groups were used to explore beliefs and attitudes about breast health, breast cancer, breast cancer prevention, medical research and ways to communicate information about research to the African American community. A convenience sample of 45 African American women without a diagnosis of breast cancer was recruited from the breast clinic at a large Los Angeles County Hospital to participate in eight focus group discussions. Findings from these discussions provided the basis for the content of items to be included in the survey questionnaire related to beliefs and attitudes about research participation, perceived benefits of and barriers to participation, referent influences, factors influencing research participation (Appendix B - Survey Questionaire).

Content analysis (18) of focus group findings revealed the following main emerging themes concerning participation in research: 1) the importance of informed consent; 2)lack of understanding regarding the placebo concept which is viewed as "unfair treatment"; 3) distrust of the research process due to feelings of being experimented on, and being used a Guinea Pig; 4) view of medical research as being important, as well as, a way to help others, and means to increase knowledge and advance science if used properly; 5) view of financial compensation as important, providing funds to assist with transportation costs and cost for child/elder care, rather than an incentive, as well as, a means for demonstrating respect and value for the participant's time and effort; and 6) perception that research is for people who have the disease, not for healthy people, with participation leading to development of the disease (Appendices d and E).

Questionnaire Development:

A questionnaire was developed guided by the focus group findings and constructs from the theoretical models. Pretesting of the questionnaire was conducted via a validation session involving the original focus group participants. A total of 20 out of 45 focus group participants returned to review the questionnaire for face validity. Redundant items were deleted and confusing statements were clarified. Subsequently, the questionnaire was reviewed by a judge panel of experts: nurse psychologist, nurse anthropologist who has experience working with the African American Population, and a physician oncologist. The judges rated each item for relevance and congruence with each content area. The content validity index (CVI) ranged from .65 to 1.00 for the individual scales with an overall CVI equal to .97. The attitude scale had the lowest content validity index, items were reviewed with the judge panel and revisions were made to incorporate expert suggestions raising the CVI for the attitude scale from .58 to .65.

The format of the questionnaire was also revised to ease completion. Although the questionnaire was lengthy, focus group participants suggested that an explanation be included in the introductory letter explaining that the questionnaire was long but that all information was very important and would be useful for developing programs to help fight the battle against breast cancer.

A pilot test was subsequently conducted recruiting African American women from the Cardiology and Breast Clinicc at the Harbor-UCLA Medical Center. Forty-five African American women completed the questionnaire while waiting in the clinic for their appointment. They were asked to complete and return a second questionnaire within one week using a postage-paid enclosed envelope to determine test-retest reliability. Only seven participants returned the second questionnaire which was not sufficient to complete the test-retest reliability. Internal consistency reliability was determined for all scales of the instrument using Cronbach's alpha for continuous variables and Kuder Richardson's 20 (KR-20) for dicotomous variables (Apendix C - Table 1).

Based on the content validity index, pilot testing and reliability determination, items were deleted for the behavioral control and referent influence scales to improve their reliability. The health behavior scale had a reliability of .18. This scale consisted of only 2 items which were mutually exclusive i.e. BSC practice and prior mammography screening which may account for the low internal consistency reliability. Data from this scale provided descriptive information only and was not used in teh multivariate analysis. The final version of the questionnaire was again reviewed by the judge panel for content validity which was determined to be .98 for the entire questionnaire. The internal consistency reliability ranged from .50 to .86 which is within the acceptable range for instruments in the early stage of research (19).

Scales

Summated Likert scales were used to measure all variables except demographic characteristics and knowledge which included multiple choice and true or false formats. The newly developed questionnaire was divided into eight parts and is included in Appendix B. Socio-demographic data (Part I) was obtained by 12 questions including items such as racial/ethnic background, education, marital status, income, insurance status usual source of medical care, and source of health information, medical history, heart disease, diabetes, hypertension and cancer, family history of breast cancer and prior research participation. Part II of the instrument contained items from Champion's Health Belief Model and Breast Cancer instrument (15) assessing perceived seriousness of breast cancer (7 items), perceived susceptibility to breast cancer (5 items), and health motivation (7 items). Two items measured breast health behavior, breast self-exam practice and mammography compliance. The sum of the items in each scale comprised the scale score, with high scores indicating greater perceived seriousness and susceptibility health motivation and breast health behavior. Internal consistency reliability coeffecients reported by Champion for seriousness, susceptibility, and health motivation were .80, .93, and .83 respectively.

The third part of the questionnaire (Part III) included the Socially Desirable Response Set (SDRS) scale which has been refined by Hays and colleagues (1989). Items were scored according instructions. Scores ranged from 0 to 5 with high scores indicating the a greater degree of socially desirable responses. Reliability for the scale previously reported by Hays et al. was .68 (20). In prior research conducted by this investigator in a population of African American pregnant women, the internal consistency reliability was .58 (21).

Part IV of the questionnaire was developed for this study and contained a 10-item multiple choice, agree - disagree (true-false) test of knowledge about breast cancer risk, screening, and signs and symptoms of breast cancer. A knowledge score was determined by summing the number of correct responses with a possible score range from 0-10. Part V of the questionnaire, also developed for this study, consisted of nine items measuring positive beliefs about medical research, ten items assessing the importance of potential benefits of research participation, twenty items identifying factors facilitating research participation, fifteen items measuring negative beliefs about research, and thirteen items assessing barriers to research participation. The sum of each of the scale items comprised the individual scale scores. The range for the possible scale scores are identified in Appendix C - Table 1.

Part VI of the questionnaire also developed for this study consisted of eight items of assessing important referent influences, one item measuring perceived general social norm regarding participation in breast cancer prevention research, two items assessing intention to participate in medical research, three items determining perceived behavioral control regarding research participation, and four items measuring general attitudes regarding medical research. Again, the sum of each of the individual scale items comprised the individual scale score with a possible range of scores reported in Appendix C - Table 1. Stage of research particiaption behavior was also measured in this section identifying individuals in various stages of research particiaption behavior: precontemplation (not thinking about research participation/not interested), contemplation (thinking about research participation and wanting more information), and preparation/action (already know about breast cancer prevention research and are interested and are already participating), as was preferred type of breast cancer research participation, i.e. diet, pill or completing questionnaires.

Part VII of the questionnaire contained nine items from Green's Racism Perception Scale adapted to reflect content related research participation. The scale was scored according to instructions. Previous internal consistency reliability for this scale reported by Green was .88 and .91(22).

Part VIII contained four items from Strayhorn's Religiousness. Previous reliability reported for this scale was .88 (23).

Data Analysis

Univariate, bivariate and multivariate techniques were used to describe the sample and identify the relative strength and interaction of factors influencing African American women's decisions to participate in breast cancer prevention research. The BMDP statistical software package was used to conduct the analysis. All cases with greater than 5% missing responses for each scale were eliminated from the analysis. Missing score data was otherwise replaced with the mean. Pearson correlations were performed to identify relationships between the outcome variables (intention and stage of research participation) and the mediating variables (attitudes, beliefs, social norms and behavioral control) and also between mediating variables and predictor variables (predisposing enabling and reinforcing factors). Differences in stage of research participation behavior based on demographic characteristics were analyzed by chi-square and analysis of variance analysis. Stepwise multiple regression was used for multivariate analyses to identify important predictors of the mediating and outcome variables. Results of $p < .05$ are reported.

Results

Respondent Characteristics (Appendix C - Table 2)

A total of 512 questionnaires (5.2 %) were returned including responses from African American women (N=311), Caucasian women (N=163), Hispanic women (N=18) and Asian/Pacific Islander women (N=20). Results reported reflect responses from 294 usable questionnaire received from African American women only.

The mean age of respondents was 54.5 years. The average number of years of education was 13.86. The majority of respondents (4.6%) were married or living together, had a yearly household income between $11,000 to $13,999 per year and had health insurance, primarily HMO. Almost 28% reported a family history of breast cancer. The majority of respondents reported interest in research programs which involve dietary change (79.9%), followed by research which required form and questionnaire completion (42.7%). Of least interest was research which involving pill taking behavior (25.4%). The majority of respondents reported no prior research participation.

Stage of Research Participation Behavior and Intention to Participate in Research (Appendix A - Diagrams 2 & 3)

The number of respondents categorized in the preparation/action stage of research participation was minimal (10%). The majority of respondents (47.6%) were in the contemplation stage with 42.6% in the precontemplation stage of research participation behavior. Intention to participate in research was measured by two items asking respondents whether they wanted to participate in breast cancer prevention research and whether they planned to do so. Over one-third of respondents reported that they wanted to participate, while only 25.4% reported that they planned to participate. The majority of respondents reported uncertainty concerning their intention to participate in BCPR.

Knowledge, Beliefs, Attitudes (Appendix C - Table 1)

Knowledge about breast cancer signs and symptoms, risk factors, and screening procedures was low. The mean knowledge score was less than 70% for African American women who responded who responded to the survey. Less than 40% of the respondents identified age over 50 as a risk factor for breast cancer with almost 80% correctly identifying family history of breast cancer as an important risk factor. Just over half (52.1%) agreed that breast cancer was the most common cancer affecting women in the United States

and just over one-third (33.6%) disagreed with the statement that few breast cancers are found by women themselves. Over 75% (76.1%) of respondents believed that breast cancer found at an early stage could be cured. Screening methods were correctly identified by 63.9% of respondents and signs and symptoms of breast cancer (painless lump, nipple discharge) were correctly identified by only 14.6%. Many women felt that a painful lump was a symptom of breast cancer.

The mean score for positive beliefs about research was 19.38 with a possible score range 0-36. The majority (92.1%) of respondents felt that research was important in order to find better ways to treat and prevent breast cancer and 88% agreed that taking part in research was important because it could help others even if it would not help oneself. Fewer respondents (67.5%) trusted that doctors and nurses doing research have the participant's interest at heart. Most respondents (60.9%) agreed or were unsure (18.5%) about whether people know about medical research. More than half of the respondents (52.1%) reported that they were not sure about, and only 22.1% agreed with the statement that medical research sponsored by the government is safe. Only 41.4% of respondents agreed that the benefits of research participation outweighed the difficulties such as taking pills, changing diet, and keeping appointments while 31.7% were uncertain about this statement.

The predominant negative beliefs about research identified by respondents included side effects (58.9%) and use of placebos (53.6%). A total of 45.6% of respondents agreed that researchers "don't always tell you want they are going to do" while 30.3% were not sure about this statement. Many respondents (43.9%) felt they did not want or were unsure (20.9%) about whether they would want to be the first to try "new things". Over one-third (35.5%) felt they would not be able to choose the treatment they wanted if they participated in research, while 34.1% were unsure about this statement. The majority (33.7%) of respondents agreed or were unsure (29.6%) if research treatment would work. Over one-third (32.9%) reported that they do not understand research. Less than a third (27.2%) reported that they would feel like a guinea pig if they participated in research. A total of 27.5% of respondents were not sure about whether participation in research might cause breast cancer. Almost one-third (29%) were uncertain and 13.4% agreed that they did not trust researchers.

The mean attitude score was 9.05 with a possible score range 0-16. The majority of respondents (73.3%) felt participation in medical research to prevent or better treat breast cancer was important. They also felt breast cancer research was effective and many respondents (51.3%) felt it was ethical, although 34.8% were unsure about whether breast cancer research was ethical. The majority of respondents (68.7%) agreed (38.5%) or were uncertain (30.2%) about the statement "I think cures for cancer are known but are not being shared with the public.

Benefits, Barriers, and Facilitating Factors (Appendix C - Table 1)

The mean benefit score was 30.75 with a possible score range 0 - 40. The predominant benefits of research participation identified by respondents included increasing knowledge about breast cancer (94.2%), careful medical follow-up 93.8%, learn more about one's own body (91.1%), possibility of preventing others from getting breast cancer (86.7%), increasing scientific knowledge (85.7%), possibly lowering one's chance of getting breast cancer (85.2%), free mammograms (62.8%) and free medical check-ups (62.5%).

The mean barrier score was 19.6 with a possible score range 0 - 52. The important barriers identified by respondents included: extra trips to the clinic (54.7%), don't like to take pills (43.9%), time (35.9%), competing responsibilities at home (27.5%, difficulty remembering to take pills (24.1%), difficulty changing diet (21.2%), no transportation (17.0%) costs (12.7%) and family does not support participation 10.3% agree, 24.4% uncertain).

The factors facilitating research participation mean score 55.56, score range (0 - 80). The important facilitating factors reported by respondents included issues related to: assuring informed consent such as

clear understanding of all possible risks (90.3%), side effects (89.4%), what is expected of the participant during the study (85.7%), and benefits of participation (85.2%). Additional factors facilitating research participation included feeling the doctor was honest about what would be done in the research program (89.3%), receiving information about the results of the research (87.9%), making programs available in the community (79.5%), offering research programs that would involve diet or exercise (78.5%), providing programs at no cost (74.5%), including free health check-ups (71.7%), perceived increase risk of developing breast cancer (67.0%), convenient visit scheduling (67.0%), combining research visits with regular doctor visits (67.0%), offering cash payments to enable subjects to do what the program requires, for example, follow a special diet (66.6%), physician recommendation 59.2%, and presentation of study information by African American or black health care professional (32.3% agree, 26.5% uncertain).

Social Norm, Referent Influence, and Behavioral Control (Appendix C - Table 1)

The social norms regarding research participation was measured by a single item. The majority of respondents (60.5%) reported uncertainty whether most people think individuals should participate in medical research. The important reference potentially influencing research participation behavior identified by respondents included other women already participating in the research program (84.9%), doctor/nurse (81.5%), family (79.9%), friends (58.6%), and pastor (25.9%). The majority (93.8%) of respondents reported they would want to get more information about the research program and subject, and 78.4% reported that they would pray about about it and ask God's help in making a decision about whether or not to participate.

The mean behavioral control score was 5.02, score range 0-12. The majority of respondents agreed that participation in a BCPR program involving changing diet (45.2%) or taking medication (42.8%) would be easy. Half (50%) of respondents were uncertain about whether it would be easy or difficult to participate in a medical research program.

Serious, Susceptibility, and Health Motivation (Appendix C - Table 1)

The mean score for perceived seriousness of breast cancer was 12.71 with a possible range 0-28. Perceptions about the seriousness of breast cancer were moderate with a majority (72.5%) of respondents agreeing that the thought of breast cancer caused fear. Over one-third (40.4%) agreed that if they developed breast cancer they would not live longer than five years. Perceived susceptibility to breast cancer was low (mean score 5.58, score range 0-20), while health motivation (mean score 23.08, score range 0-28) was high.

Health Behavior (Appendix C - Table 1)

The majority (59.8%) of women reported doing breast self exam at least once every month and 87.3% reported that they had at least one mammogram in their lifetime.

Racism and Religiousness (Appendix C - Table 1)

Perceptions of racism were moderate (mean score 13.93, score range 0-36) while religiousness was high (mean score 16.41, score range 4-20).

Identification of Important Predictors (Appendix C - Tables 3 - 8 and Appendix A - Diagrams 4 & 5)

A series of stepwise multiple regression analyses were conducted to identify the significant predictors of research participation, intention, positive beliefs about research, negative beliefs about research, behavioral control, and social norms regarding research participation behavior. Important predictors, explaining 29% of the variability in stage of research participation behavior included intention to participate, negative beliefs about research, general social norm regarding research participation,

insurance status, benefits of research participation, and barriers to research participation (Table 3 and Diagram 4).

Significant predictors explaining 30% of the variability in intention included behavioral control, negative beliefs, positive beliefs, social norm, insurance status, and benefits (Table 4 and Diagram 5)

Signfifcant predictors explaining 30% of the variability in positive beliefs about research participation included family history of breast cancer, prior research participation, knowledge, health motivation, perceived seriousness of breast cancer, referent influence, religiousness and perceived benefits of research participation (Table 5). Significant predictors explaining 36.5% of the variability in negative beliefs about research included education, marital status, perceived seriousness of breast cancer, referent influence, racism, benefits, and barriers (Table 6).

Significant predictors explaining 12% of the variability in behavioral control regarding research participation included education, prior research participation, seriousness, benefits, and barriers (Table 7). Finally, benefits explained 3% of the variability in social norms regarding breast cancer prevention research participation (Table 8).

Based on these findings, the important predictors of research participation included those factors that have both direct and indirect influences on intention and stage of research participation behavior. Predictor variables having the strongest influence included perceived benefits of research participation, perceived seriousness of breast cancer, barriers to research participation, referent influence, insurance status, prior research participation, religiousness, family history of breast cancer, health motivation, marital status, and education. Mediating variables having the strongest influence include negative beliefs about research participation and social norms regarding research participation both of which exert a direct influence on stage of research participation behavior as well as an indirect influence via intention. Behavioral control and positive beliefs about research exert only an indirect effect on stage of research participation behavior via intention.

Of the predictor variables, benefits exerted the greatest impact having a direct influence on research participation behavior and an indirect influence via intention, negative beliefs, positive beliefs, social norms and behavioral control. Barriers also exerted a strong influence on research participation behavior having a strong direct influence on research participation behavior, as well as, an indirect influence via negative beliefs and behavioral control. Perceived seriousness of breast cancer exerted an indirect influence on research participation behavior via negative beliefs, positive beliefs and behavioral control. Insurance status exerted a direct influence on stage of research participation behavior, as well as, an indirect influence via intention. Education exerted an indirect influence on research participation behavior via negative beliefs and behavioral control, and referent influence exerted an indirect influence on research participation behavior via negative beliefs and positive beliefs.

Discussion and Implications

The purpose of this research was to identify the factors influencing African American women's decisions to participate in BCPR clinical trials including knowledge and beliefs about breast cancer, awareness of and beliefs about medical research, and preferred type of research participation behavior. It was important that a range of responses to intention to participate in BCPR and stage of research particiaption behavior was obtained. The majority of African American women reported interest or had thought about BCPR, however many were unsure about wanting or planning to participate. This may in part be due to the hypothetical nature of the questions in the survey not identifying a particular research program, therefore making it difficult for rtespondents to decide whether they would want to participate.

Several important factors influencing research participation behavior and intention to participate were identified in this study providing support for the previously identified assumptions regarding factors

influencing African American participation in medical research (7,8,9), as well as, identifying specific strategies that could be incorporated into recruitment plans to increase African American women's participation in BCPR programs.

Predictor Variables

Evidence showed a lack of knowledge regarding breast cancer risk, detection, and signs and symptoms of breast cancer, as well as, lack of awareness of ongoing breast cancer prevention clinical trials. Knowledge was also identified as an important predictor of positive beliefs about research. Including information about breast cancer risk, detection, and signs and symptoms of breast caner may help to increase positive beliefs about BCPR and consequently influence intention to participate.
Perceived seriousness of breast cancer was another important predictor of positive and negative beliefs about research participation and behavioral control. These findings suggest that information regarding the severity of the breast cancer problem, especially as it affects the African American community, needs to be included when educating African American women about breast cancer prevention research trials. Perceptions regarding the seriousness of breast cancer were positively associated with both positive and negative beliefs about participation in breast cancer prevention research, thus, one would be concerned that a threshold effect might exist. The amount and type of information which may impact perceptions regarding the seriousness of breast cancer needs further investigation to be able to develop effective communication messages regarding the seriousness of breast cancer. Excessive "negative" information may further fuel the fatalistic attitude about breast cancer which is prevalent in the African American community (24) and result in an increase in negative beliefs about breast cancer prevention research participation. Many respondents (40.4%) felt that they would not be alive in five years if they were diagnosed with breast cancer. It would be important to emphasize the effectiveness of early detection and screening and the potential for cure if breast cancer is diagnosed early. In addition, a better understanding of the factual information regarding breast cancer statistics in the African American community may impact perceptions of seriousness of breast cancer which could influence beliefs about research participation and perceived behavioral control or perceived ability to participate in a breast cancer prevention research program.

Demographic characteristics, education, insurance status, and prior research participation were the primary respondent characteristics identified as important predictors of research participation behavior. Higher levels of education were associated with increased behavioral control or perceived ability to participate in BCPR trials, while lower levels of education were associated with more negative beliefs about breast cancer prevention research. These findings support previously reported results regarding low levels of education as a barrier to research participation (8).

Having no health insurance was positively associated with research participation while having health insurance was negatively associated with particiaption. This is not a new finding, however, the reasons for the lack of participation by those with health insurance needs to be explored. Perhaps, those with insurance are concerned about whether participation would affect their insurance coverage. In our own experience, endorsement of a breast cancer prevention research program by an insurance carrier greatly increased the interest response rate for potential participation in the Womens Health Initiative.

Not surprisingly, prior research participation was also an important positive predictor of positive beliefs about research and perceived behavioral control. Those with prior experience with research participation reported more positive beliefs about research participation and also greater behavioral control or perceived ability to participate.

The most important predictor of research participation behavior was perceived benefits. Benefits influenced research participation and intention directly and indirectly via positive and negative beliefs about research, social norm and behavioral control. Greater perceived benefits of research participation were associated with greater research participation behavior, more positive intention to participate,

positive beliefs about research, social norm, and behavioral control and fewer negative beliefs about research participation. This suggests that perceived benefits of research participation is a potentially powerful predictor of research participation behavior. Including explanations of the benefits of participation in a particular research program would be critical.

Barriers to research participation were also important as they negatively influenced research participation directly and indirectly via behavioral control. Barriers also negatively influenced research participation behavior indirectly via negative beliefs. Increased barriers were associated with decreased research participation behavior and decreased perceived ability to participate (behavioral control) and were positively associated with negative beliefs about research. This suggests that perceived barriers may be another powerful predictor of research participation behavior. Identifying and overcoming the specific barriers to research participation for a particular study for the target population of interest would also be critical for the successful completion of the proposed research (25,26,27).

Factors having no impact on mediating or outcome variables included age, physician recommendation, health behavior (breast self examination, mammography) and factors facilitating research participation behavior. Although facilitating factors did not emerge as significant predictors, findings identify important strategies that could be included in the design of recruitment strategies to improves accrual of African American women.

An area for further investigation includes exploring the role of health insurance in breast cancer prevention research participation. Numerous reports of the difficulties of receiving "prior authorization" for research treatment protocols and even standard procedures have been heard by many. Concerns of insurance carriers must also be explored, as this may be an important factor impacting breast cancer prevention research trial participation.

Mediating Variables

Among the mediating variables, negative beliefs and social norms exerted the strongest influence having direct effects on research participation, as well as, indirect effects via intention. Negative beliefs were negatively associated with both research participation and intention while social norm regarding research participation was positively associated with research participation and intention.

Limitations

It is well recognized that results from any survey of this nature may be influenced by self-selection toward the subject matter and consequently generalizability may be limited to the sample of African American women who responded to the survey. The low response rate (5.2%) further limits the generalizability of study findings, as does conducting the survey in a single geographic location which means findings may not be generalized to African American women across the country.

An unknown problem in using purchased mailing lists identifying a particular segment of the population was potentially responsible for the low return rate. Although a listing of 10,000 African American women's names was purchased, once questionnaires began to be returned, a substantial number of responses were returned for Caucasian, Hispanic, and Asian/Pacific Islander women (a total of 201 responses) which was not included in this analysis. Upon discussion with the mailing list supplier, it was noted that as much as a 20% error rate can exist in such race specific mailing list and therefore it is not possible to exactly determine the number of African American women to whom a mail survey was sent which certainly could affect the response rate. In any event, the total response rate of 5.2% is similar to the response to mass mailings involving a return of an interest survey which has been used for recruitment to the Womens Health Initiative nationwide using similarly purchased mailing lists. Little information is reported in the literature regarding response rates to mailed surveys involving minority populations therefore, it is difficult to compare and interpret the response rate in this study.

A positive outcome of this problem, however, is the ability to conduct a comparative analysis examining the similarities and differences in views on research participation between African American and Caucasian women which has been done and is included as an abstract in Appendix F. In addition, analysis of characteristics of respondents including African American women and Caucasian women in the various stages of research participation behavior has also been completed and has been included in Appendix G.

Conclusions

Based on findings from this research recommendations for developing strategies for recruiting African American women to breast cancer prevention trials have been identified. These should focus on: 1) reversing negative beliefs about research participation by clarifying issues related to randomization, use of placebo, side effects, risks and benefits, and having persons in the program assist with publicizing the study when possible; 2) gaining endorsement of the program by important referents such as health care providers and family members; 3) identifying and eliminating barriers to the specific research program such as indicating the upper age limit for participation (individuals may not be "too old"), assuring informed consent, combine research visits with regular health care visits to reduce the need for extra trips, informing the potential participant of the time commitment, and offering flexible hours; 4) gain endorsement of the program by insurance carriers; being aware that African American women without insurance may be more apt to participate in research programs, African American women with insurance may be uncertain about whether participation may affect their insurance coverage or require additional charges; and 5) the strong influence of perceived benefits suggests that communication messages aimed at promoting advantages of research participation may be a powerful means for enhancing African American women's participation.

Recommendations in Relation to the Statement of Work:

All tasks identified in the original statement of work were completed as planned except for the conduct of the mail survey. As recruitment for WHI was problematic at the time of the conduct of the mail survey, it was decided to increase the the mailing list sample to 10,000 because of the low response rates we were receiving from the mailings for WHI recruitment. The average response to use of WHI brochures with a post card return was 1.0%. Therefore, it was estimated that to receive a response rate that allowed at least a multivariate analysis to identify factors influencing decisions to participate in BCPR trials, a mailing to 10,000 women was conducted. We recognized that generalizability would be a problem but at least would gain insight regarding the factors influencing research particiaption. We did not anticipate a return from a large proportion of responders who were not African American. A positive outcome from this unexpected event, since a substantial response was received from caucasian women, was a comparative analysis of African American and Caucasian women's views on breast cancer and BCPR participation (Appendix F).

Followup and tracking of responders related to WHI participation was also not conducted due to concerns about maintaining anonymity. It was also difficult to identify whether individuals received the survey questionnaire for this study as numerous other similar studies were being conducted in the same geographic area. By incorporating a stage of research particiaption behavior question, however, it was possible to assess individuals in varying stages of research particiaption behavior and the distribution of responses spanned the varying stages.

Future research in this area would benefit from expanding the geographic area and increasing the size of the mailing list to account for the multicultural representation which exists in our country, particularly in the southern California area.

Activities During the Training Period

During year one an abstract entitled "Attitides and Adherence of African American Women to Dietary Fat

Intake Reduction" was presented at the Oncology Nursing Society 20th Annual Congress in Anaheim, California in May, 1995 (Oncology Nursing Forum, 1995, 22(2):373 - Appendix H). In year two, as more of the proposed research was conducted, a subsequent abstract entitled "African American Perspectives on Research Participation: Emerging Themes" and manuscript entitled "African American Women's Perspectives on Research Particiaption" were completed related to findings from the focus group discussions (Appendices D & E). This work was nominated for the Oncology Nursing Society/Schering Excellence in Cancer Nursing Research Award and was presented at the Advanced Nursing Researh Session of the Oncology Nursing Society Annual Congress in Philadelphia, May, 1996. A poster presentation of the focus group findings was also presented at the national conference on Minority Recruitment to Clinical Trials held in Washington, D.C., January, 1996.

In addition to the research presentations, an instructional session entitled "Insider/Outsider Perspectives in the Conduct of Research in Special Populations" was presented at the Oncology Nursing Society Annual Congress in May, 1996. I was also invited to speak about minority recruitment at the National Nutritionists Training Session for the Women's Intervention Nutrition Study, a multi-site clinical trial evaluating the impact of a low-fat diet on breast cacner recurrence. I was also invited to particiapte in a writing group as part of the Women's Health Initiative addressing the issue of the impact of insurance status on research participation.

During year two, the efforts of this current, as well as, previous research were recognized by nursing colleagues at our institution. I received the Outstanding Nursing Achievement Award for 1996 at the Harbor-UCLA Medical Center. Finally during the second year of fellowship training, I was appointed as Chair of the Research Committee for the Oncology Nursing Society having been a member of this committee and study section reviewing small grant and fellowship applications, and abstracts for congress presentation for the previous four years.

In year three, findings from the mail survey regarding factors influencing African American Women's decisions to participate in BCPR were presented at the 6th Biennial Symposium on Minorities, the Medically Underserved and Cancer in Washington, D.C. April, 1997 (Appendix I). A scholarship was received to attend this conference based on the merit of the research. The abstract is also in press in the journal Cancer Research Therapy and Control. In addition to the national research presentation, I was invited to present Grand Rounds at Martin Luther King-Drew Medical Center in the Los Angeles area regarding the topic of Minority Recruitment to Clinical Trials.

As a result of the research conducted as part of this training fellowship and the experience gained in the conduct of national multisite clinical trials involving dietary modification (Women's Health Initiative and the Women's Intervention Nutrition Study), I developed a proposal focused on the development of tailored messages to enhance adherence and retention in long term clinical trials involving a dietary component which includes similar methodology to that conducted in the fellowship research and incorporates findings which may not only impact recruitment but also retention and adherence in breast cancer clinical trials. This application was submitted to the Department of Defense as a dual submission (Career Development Award and Idea Award) in June, 1997.

At the completion of the training fellowship I will remain in a position at Harbor-UCLA Medical Center, Division of Medical Oncology in the capacity of a Research Associte and will be Project Director for the continuing Women's Health Initiative (WHI) and Director of Minorty Recruitment for the Women's Intervention Nutrition Study (WINS). I am also co-investigator on a newly awarded small seed grant which will involve the conduct of focus group discussions with participants in the WHI and WINS studies to identify factors which influence dietary adherence and continued study participation.

The fellowship support during the last three years has been very helpful in allowing me to take advantage of the numerous opportunities available in the WHI and WINS studies to begin to develop an independent, behaviorally focused breast cancer research career.

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Diagram 1
THEORETICAL FRAMEWORK

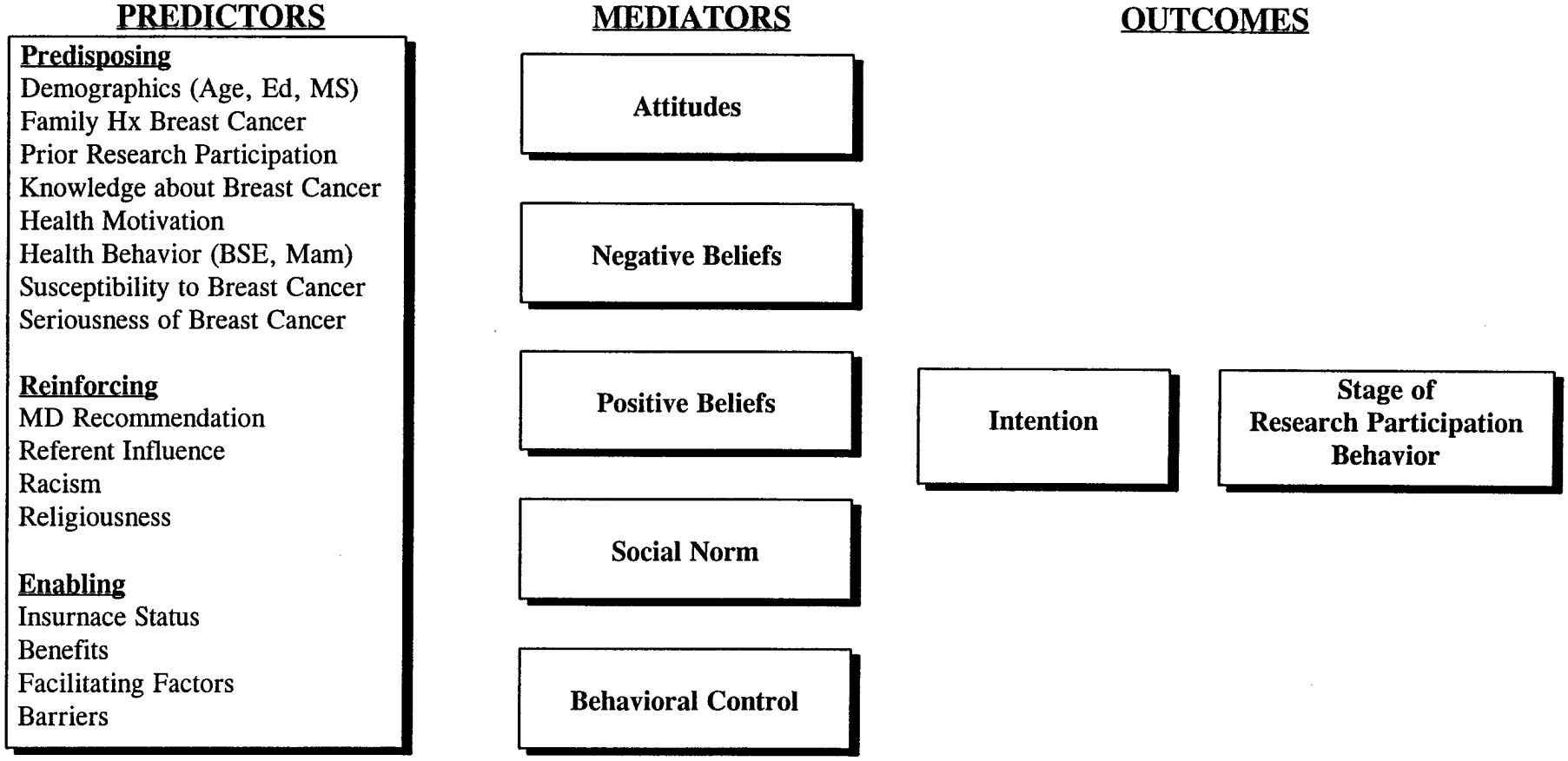


Diagram 2
Stage of AAW's Research Participation

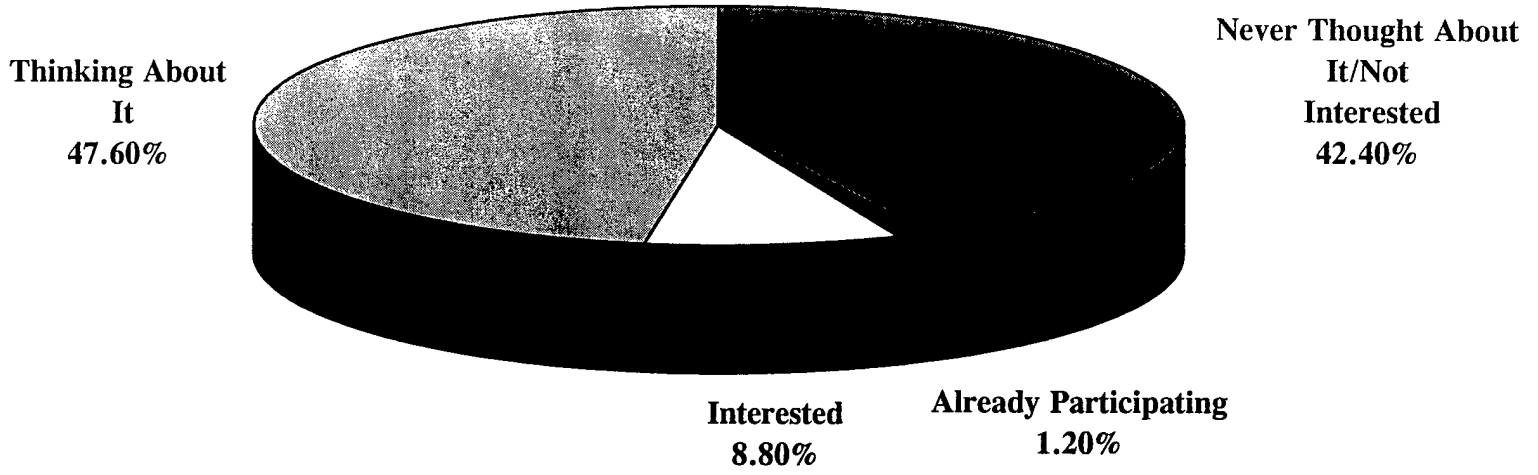
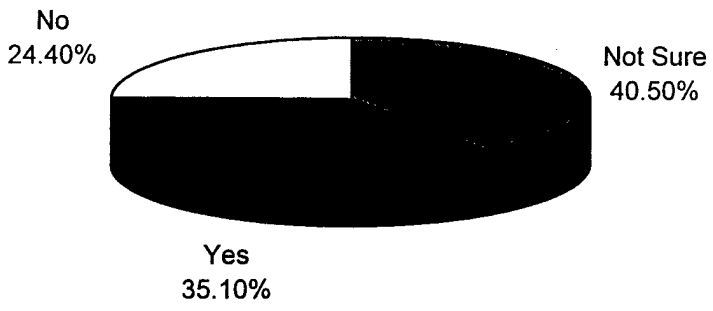


Diagram 3 Intention

WANT To Participate



PLAN To Participate

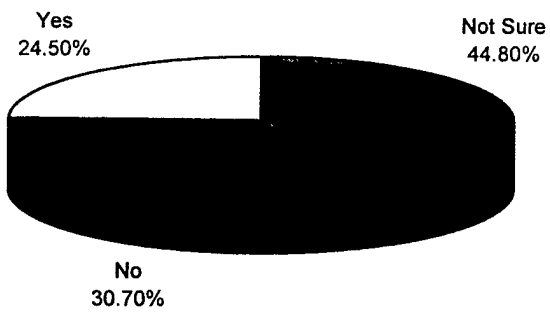


Diagram 4

PREDICTORS OF RESEARCH PARTICIPATION

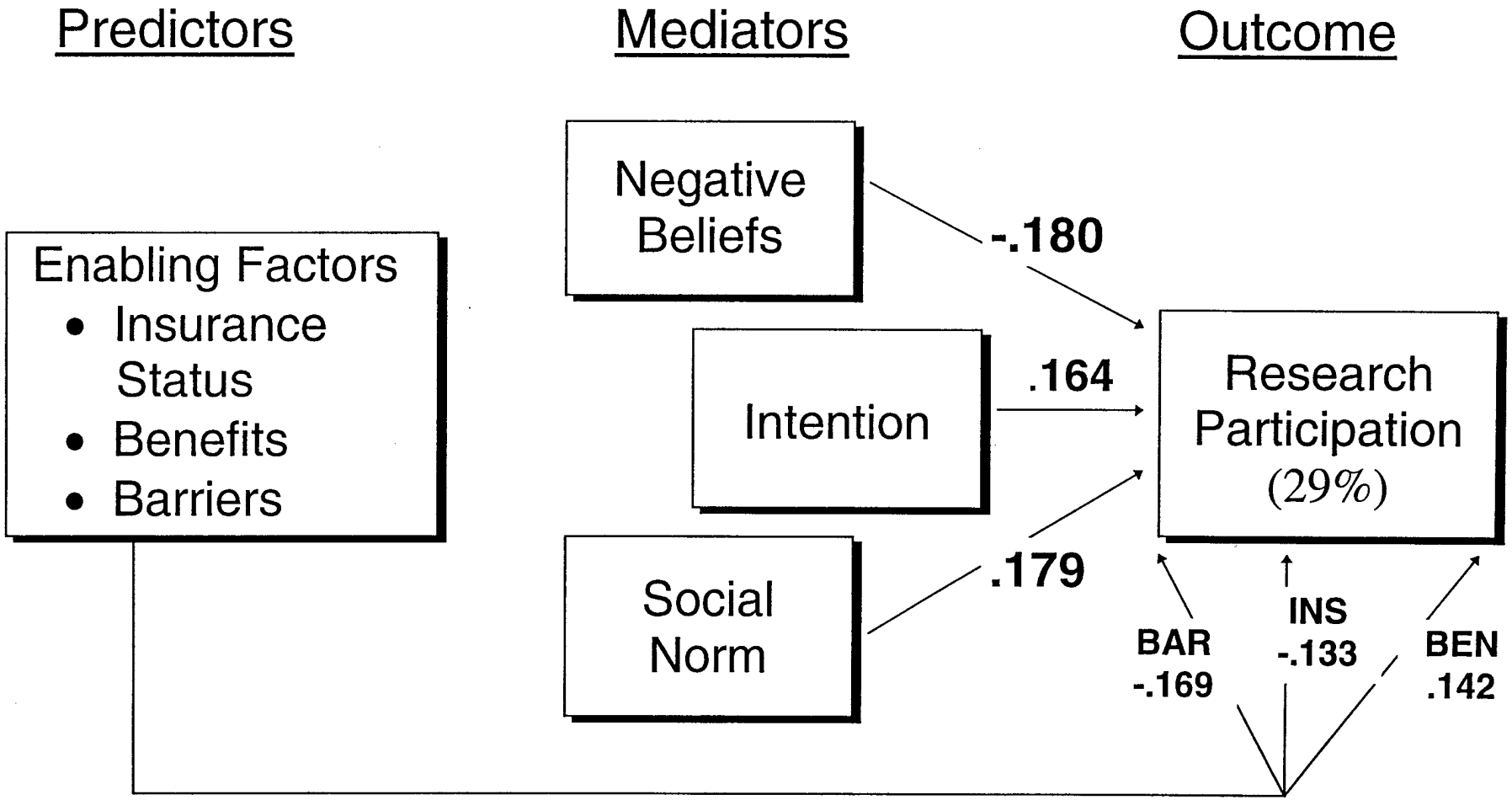
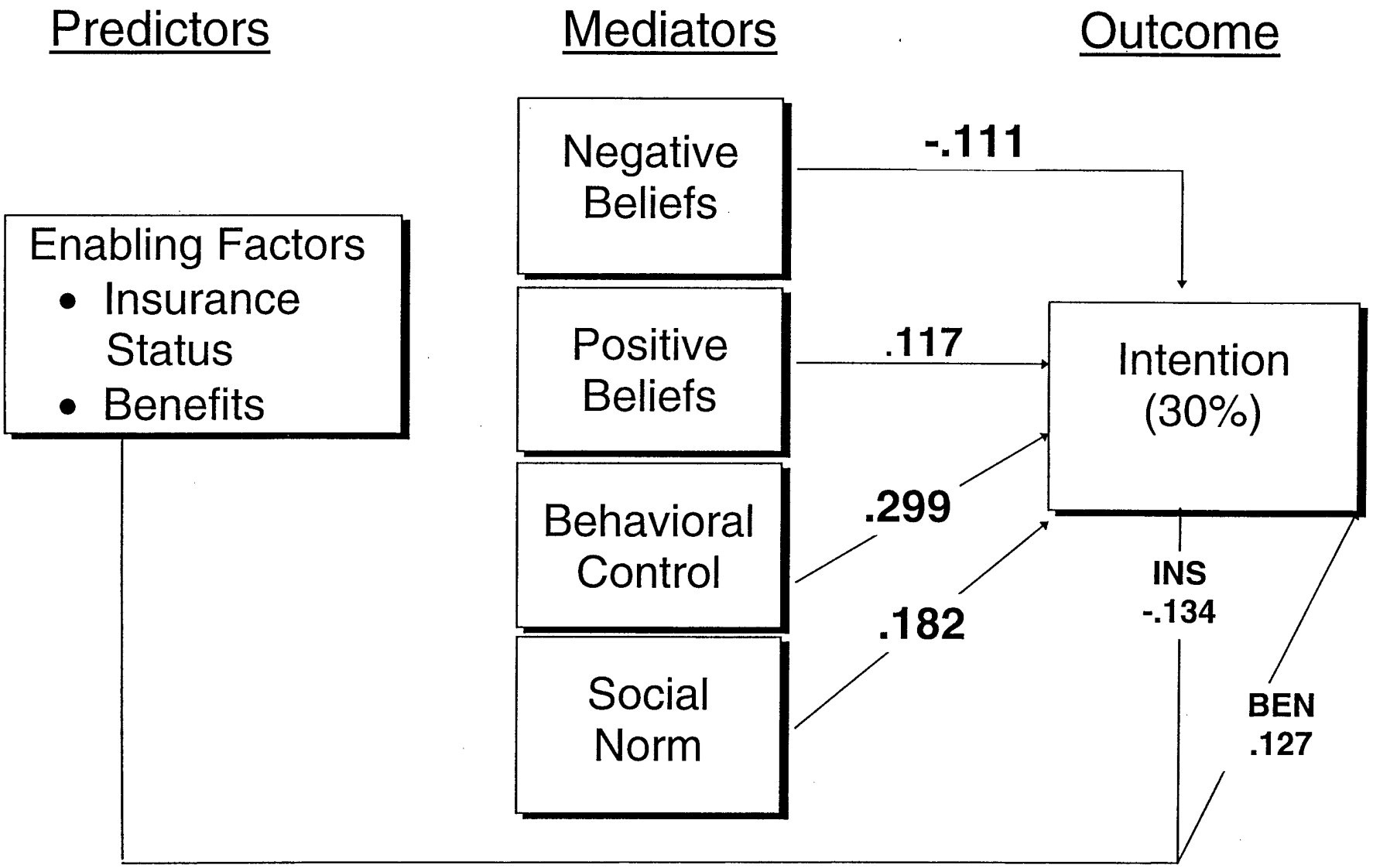


Diagram 5

PREDICTORS OF INTENTION



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DIVISION OF MEDICAL ONCOLOGY
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509

(310) 222-2217

Women's Thoughts About Breast Cancer

Thank you for agreeing to answer these questions about breast cancer. We are interested in learning how women like yourself feel about breast cancer and Medical Research. Although this is a long questionnaire, your responses are appreciated and will be very useful for developing programs to help Black women learn more about breast cancer and ongoing research.

There are no right or wrong answers, only your important thoughts and opinions. We are interested most in what you really think and what you really do, not what you think you "should do." Please answer **EVERY** question as best you can. Your name is not identified on this questionnaire. All responses are totally confidential (secret). An addressed, postage paid envelope is enclosed for return of the questionnaire. We would appreciate your returning your response by **February 29, 1996.**

If you need any help in completing the questionnaire or have any questions, we would be happy to assist you over the phone. You may call Linda or Barbara at (310) 222-2217 or (310) 222-2219. Again, every woman's thoughts and opinions are important to us. We appreciate your time and effort in completing the questionnaire. This is an opportunity for you to help fight the battle against breast cancer for yourself, your daughters and generations of women to come.

For Office Use Only

Date:___/___/_____
IDC:_____

Part I

These questions ask for some information that will help us to know more about the women who answer the survey. **PLEASE CIRCLE THE NUMBER THAT BEST DESCRIBES YOUR ANSWER OR FILL IN THE BLANKS.**

1. What is your birthdate?

   _____/_____/_____
   mo day yr

2. What is your zip code?

   _____/_____/_____/_____/_____

3. What is your racial/ethnic background?

   1 - Black
   2 - African American
   3 - White
   4 - Hispanic/Latino
   5 - Asian - Pacific Islander
   6 - Other_____
   (Specify)

4. How many years of school have you finished? **(Please circle highest grade completed)**

Elementary	1 2 3 4 5 6 7 8
High School	9 10 11 12
College	13 14 15 16
Graduate School	17 18 19 20

5. What is your marital status?

   1. Single, never married
   2. Living together as married
   3. Married
   4. Separated/Divorced
   5. Widowed

6. What is your yearly household income?

   1. Less than $5,000
   2. $5,000 - $10,999
   3. $11,000 - $20,999
   4. $21,000 - 30,999
   5. $31,000 - $39,999
   6. $40,000 - $50,000
   7. More than $50,000

PLEASE GO TO NEXT PAGE

7. What type of health insurance do you have?

1. MEDICARE
2. HMO
3. MEDI-CAL
4. Private Insurance
5 MEDICARE & MEDI-CAL
6. No Insurance
7. MEDICARE & Private Insurance
8. Other_____ (Specify)

8. Where do you usually receive medical care?

1. Private doctor
2. County clinic
3. Emergency Room
4. HMO
5. Other_____ (Specify)

9. Where do you usually get information about health? **(CIRCLE ALL THAT APPLY)**

1. Doctor/Doctor's Office
2. Newspaper/Magazine
3. Word of mouth (friends, family, etc.)
4. Television
5. Radio
6. Other_____ (Specify)

10. Have you ever been told you have any of the following health problems?

1. Heart disease	No___	Yes___
2. Diabetes (Sugar in blood)	No___	Yes___
3. High blood pressure	No___	Yes___
4. Cancer	No___	Yes___ (If yes, type_____)

11. Has anyone in your family ever had breast cancer?

No____ Yes____If yes, specify:

1. Mother
2. Sister
3. Grandmother
4. Aunt
5. Daughter
6. Other_____

PLEASE GO TO NEXT PAGE

Part II

This set of questions asks your thoughts and opinions about health behavior and breast cancer. **PLEASE CIRCLE ONE NUMBER ON EACH LINE.**

		Disagree	Somewhat Disagree	Not Applicable/ Not Sure	Somewhat Agree	Agree
12.	I want to discover health problems early.	1	2	3	4	5
13.	Maintaining good health is extremely important to me.	1	2	3	4	5
14.	I search for new information to improve my health.	1	2	3	4	5
15.	I feel it is important to carry out activities that will improve my health.	1	2	3	4	5
16.	I eat well balanced meals.	1	2	3	4	5
17.	I exercise at least 3 times a week.	1	2	3	4	5
18.	I have regular health check-ups even when I am not sick.	1	2	3	4	5
19.	I do breast self-exam at least once every month.	1	2	3	4	5
20.	I have had at least one mammogram in my lifetime.	1	2	3	4	5
21.	Is it extremely likely that I will get breast cancer in the future.	1	2	3	4	5
22.	I feel I will get breast cancer in the future.	1	2	3	4	5
23.	There is a good possibility I will get breast cancer in the next 10 years.	1	2	3	4	5
24.	My chances of getting breast cancer are great.	1	2	3	4	5
25.	I am more likely than the average woman to get breast cancer.	1	2	3	4	5
26.	I have no control over whether I will get breast cancer.	1	2	3	4	5

PLEASE GO TO NEXT PAGE

		Disagree	Somewhat Agree	Not Applicable/ Not Sure	Somewhat Agree	Agree
27.	The thought of breast cancer scares me.	1	2	3	4	5
28.	When I think about breast cancer, my heart beats faster.	1	2	3	4	5
29.	I am afraid to think about breast cancer.	1	2	3	4	5
30.	Problems I would experience with breast cancer would last a long time.	1	2	3	4	5
31.	Breast cancer would threaten a relationship with my boyfriend, husband or partner.	1	2	3	4	5
32.	If I had breast cancer, my whole life would change.	1	2	3	4	5
33.	If I developed breast cancer, I would not live longer than 5 years.	1	2	3	4	5

Part III

Listed below are a few statements about your relationships with others. **HOW MUCH IS EACH STATEMENT TRUE OR FALSE FOR YOU? (CIRCLE ONE NUMBER ON EACH LINE).**

		Totally True	Mostly True	Don't Know	Mostly False	Totally False
34.	I am always courteous even to people who are disagreeable.	1	2	3	4	5
35.	There have been times when I took advantage of someone.	1	2	3	4	5
36.	I sometimes try to get even rather than forgive and forget.	1	2	3	4	5
37.	I sometimes feel resentful when I don't get my way.	1	2	3	4	5
38.	No matter who I'm talking to, I'm always a good listener.	1	2	3	4	5

PLEASE GO TO NEXT PAGE

Part IV

Some women have different thoughts about breast cancer risk. **PLEASE READ EACH STATEMENT BELOW AND TELL US IF YOU AGREE, DISAGREE OR ARE NOT SURE HOW YOU FEEL ABOUT EACH STATEMENT.**

39. Which of the following are risk factors or conditions that may increase a women's chance of developing breast cancer?

a) Age over 50 years	1. Agree	2. Not Sure	3. Disagree
b) Large breasts	1. Agree	2. Not Sure	3. Disagree
c) Family history of breast cancer	1. Agree	2. Not Sure	3. Disagree
d) Injury to breast	1. Agree	2. Not Sure	3. Disagree
e) Obesity (overweight)	1. Agree	2. Not Sure	3. Disagree

40. Breast cancer is the most common cancer affecting women in the United States.

1. Agree 2. Not Sure 3. Disagree

41. Few breast cancers are found by women themselves.

1. Agree 2. Not Sure 3. Disagree

42. Breast cancer found at an early stage can be cured.

1. Agree 2. Not Sure 3. Disagree

43. Which of the following exams are used to find breast cancer? **(PLEASE CIRCLE ALL THAT APPLY).**

1. Chest X-ray
2. Mammogram
3. Breast Self-Exam
4. Bone Scan
5. Breast Exam Performed by Doctor or Nurse

44. Signs and symptoms of breast cancer include; **(PLEASE CIRCLE ALL THAT APPLY).**

1. Painful Breast Lump
2. Painless Breast Lump
3. Chest Pain
4. Nipple Discharge

PLEASE GO TO NEXT PAGE

PART V

45. The following questions ask your thoughts and opinions about Medical Research. **PLEASE CIRCLE ONE NUMBER ON EACH LINE:**

		Disagree	Somewhat Disagree	Not Sure	Somewhat Agree	Agree
a)	Taking part in research would make me feel better physically.	1	2	3	4	5
b)	Taking part in research would be important for my health.	1	2	3	4	5
c)	Benefits of being in a research study outweigh any difficulties such as taking pills, making changes in diet and keeping clinical appointments.	1	2	3	4	5
d)	Medical Research sponsored by the Government is safe.	1	2	3	4	5
e)	Taking part in a research study is important because it could help others even if it does not help me.	1	2	3	4	5
f)	I trust doctors and nurses doing the research have my best interest at heart.	1	2	3	4	5
g)	Research is important in order to find better ways to prevent and treat breast cancer.	1	2	3	4	5
h)	People who take part in research are admired by others.	1	2	3	4	5
i)	Most people do not know about Medical Research.	1	2	3	4	5

PLEASE GO TO NEXT PAGE

46. Please rate how important each of the following **BENEFITS** of being in a research study would be to you **(CIRCLE ONE NUMBER ON EACH LINE):**

		Not Important	Slightly Important	Not Sure	Very Important	Extremely Important
a)	Careful medical followup.	1	2	3	4	5
b)	Possibility of lowering my chance of getting or dying from breast cancer.	1	2	3	4	5
c)	Possibility of preventing others from getting breast cancer.	1	2	3	4	5
d)	Increasing my knowledge about breast cancer.	1	2	3	4	5
e)	Increasing scientific knowledge.	1	2	3	4	5
f)	Feel good about myself because I would be part of a research effort.	1	2	3	4	5
g)	Less worry about breast cancer.	1	2	3	4	5
h)	Learning more about my own body.	1	2	3	4	5
i)	Free medical check-ups.	1	2	3	4	5
j)	Free mammograms	1	2	3	4	5

PLEASE GO TO NEXT PAGE

47. Participation in Medical Research **WOULD BE OF INTEREST** to me if **(CIRCLE ONE NUMBER ON EACH LINE):**

		Disagree	Somewhat Disagree	Not Sure	Somewhat Agree	Agree
a)	There was no cost to me.	1	2	3	4	5
b)	I received cash payment for my time.	1	2	3	4	5
c)	Free health check-ups were included in the program.	1	2	3	4	5
d)	I Received cash payment for transportation costs.	1	2	3	4	5
e)	I had a high risk of developing breast cancer.	1	2	3	4	5
f)	I received cash payment for child or elder care so that I could attend required visits.	1	2	3	4	5
g)	My doctor recommended that I participate.	1	2	3	4	5
h)	The programs were available during evening or weekend hours.	1	2	3	4	5
i)	I received information about the results of the research.	1	2	3	4	5
j)	I received cash payment to help me do what the program requires (e.g. follow a special diet)	1	2	3	4	5
k)	I felt the doctor was honest about what would be done in the research program.	1	2	3	4	5
l)	The research program involved diet or exercise.	1	2	3	4	5
m)	Research visits could be scheduled during my regular doctor or clinic visits.	1	2	3	4	5

PLEASE GO TO NEXT PAGE

Participation in Medical Research **WOULD BE OF INTEREST** to me if:

		Disagree	**Somewhat Disgree**	**Not Sure**	**Somewhat Agree**	**Agree**
n)	I had a clear understanding of all the possible risks that might be involved in the research.	1	2	3	4	5
o)	I had a clear understanding of of all the possible side effects that might occur.	1	2	3	4	5
p)	The program involved taking a medication by mouth only.	1	2	3	4	5
q)	Information about the program was presented by African American or Black health care personnel.	1	2	3	4	5
r)	I had a clear understanding of what would be expected of me during the research study.	1	2	3	4	5
s)	I had a clear understanding of all the possible benefits that might result from taking part in the research.	1	2	3	4	5
t)	The program was available in my local community.	1	2	3	4	5

PLEASE GO TO NEXT PAGE

48. Participation in Medical Research would **NOT** be of interest to me because: **(CIRCLE ONE NUMBER ON EACH LINE)**

	Disagree	Somewhat Disagree	Not Sure	Somewhat Agree	Agree
a) I would feel like I was a guinea pig.	1	2	3	4	5
b) I would not know if the research treatment would work.	1	2	3	4	5
c) I might get breast cancer by taking part in the research.	1	2	3	4	5
d) I don't trust researchers.	1	2	3	4	5
e) I don't want to be experimented on.	1	2	3	4	5
f) There might be side effects of the medication.	1	2	3	4	5
g) It might cause pain, (e.g., blood drawing).	1	2	3	4	5
h) I don't want to be given "fake" medication (placebo).	1	2	3	4	5
i) I would not be able to choose the treatment I want.	1	2	3	4	5
j) It might cause breast cancer.	1	2	3	4	5
k) Researchers don't always tell you what they are going to do.	1	2	3	4	5
l) I don't want to be the "first" to try new things.	1	2	3	4	5
m) I just don't understand research.	1	2	3	4	5
n) I don't want to think about breast cancer.	1	2	3	4	5
o) I think Medical Research is for people who have a disease not for healthy people.	1	2	3	4	5
p) I don't trust research sponsored by the government.					

PLEASE GO TO NEXT PAGE

49. Participation in Medical Research would be **HARD** for me because **(CIRCLE ONE NUMBER ON EACH LINE):**

		Disagree	Somewhat Disagree	Not Applicable/ Not Sure	Somewhat Agree	Agree
a)	I don't have the time.	1	2	3	4	5
b)	It may require extra trips to the hospital or clinic.	1	2	3	4	5
c)	I don't have transportation.	1	2	3	4	5
d)	I have too many other responsibilities at home (caring for children, relatives).	1	2	3	4	5
e)	I don't like to take pills.	1	2	3	4	5
f)	I would have a hard time changing my diet.	1	2	3	4	5
g)	I would have a hard time remembering to take pills every day.	1	2	3	4	5
h)	My family does not want me to participate.	1	2	3	4	5
i)	My friends to not want me participate.	1	2	3	4	5
j)	I'm too old to participate.	1	2	3	4	5
k)	I'm too sick to participate.	1	2	3	4	5
l)	I'm too tired to participate.	1	2	3	4	5
m)	It would cost too much money.	1	2	3	4	5

PLEASE GO TO NEXT PAGE

Part VI

This set of questions asks your thoughts and opinions about participating in Medical Research. **PLEASE CIRCLE ONE NUMBER ON EACH LINE:**

50. If you were thinking about participating in a Medical Research program to prevent breast cancer, would you:

		No	Probably Not	Not Sure	Probably Yes	Yes
a.	Discuss it with your doctor/nurse.	1	2	3	4	5
b.	Think about it by yourself.	1	2	3	4	5
c.	Discuss it with your pastor.	1	2	3	4	5
d.	Discuss it with your family.	1	2	3	4	5
e.	Discuss it with your friends.	1	2	3	4	5
f.	Pray about it and ask God's help in making a decision.	1	2	3	4	5
g.	Get more information about the subject.	1	2	3	4	5
h.	Want to talk to other women already in the research program.	1	2	3	4	5
51.	Do most people who are important to you think you should participate in Medical Research for breast cancer?	1	2	3	4	5
52.	Do you want to participate in Medical Research for breast cancer?	1	2	3	4	5
53.	Do you plan to participate in in Medical Research for breast cancer?	1	2	3	4	5

54. How easy or hard would it be for you to participate in a Medical Research program?

1.	2.	3.	4.	5.
Very Hard	Mostly Hard	Not Sure	Mostly Easy	Very Easy

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55. How easy or hard would it be for you to participate in a Medical Research program that involved making changes in your diet?

1.	2.	3.	4.	5.
Very Hard	Mostly Hard	Not Sure	Mostly Easy	Very Easy

56. How easy or hard would it be for you to participate in a Medical Research program that involved taking a medication by mouth every day?

1.	2.	3.	4.	5.
Very Hard	Mostly Hard	Not Sure	Mostly Easy	Very Easy

57. Participating in Medical Research to prevent or better treat breast cancer would be:

1.	2.	3.	4.	5.
Very Unimportant	Mostly Unimportant	Not Sure	Mostly Important	Very Important

58. I think cures for cancer are known but are not being shared with the people?

1.	2.	3.	4.	5.
Disagree	Somewhat Disagree	Not sure	Somewhat Agree	Agree

59. I think breast cancer research is ethical.

1.	2.	3.	4.	5.
Disagree	Somewhat Disagree	Not sure	Somewhat Agree	Agree

60. I think breast cancer research is effective.

1.	2.	3.	4.	5.
Disagree	Somewhat Disagree	Not sure	Somewhat Agree	Agree

PLEASE GO TO NEXT PAGE

61. Which of the following statements best describes <u>your</u> participation in Medical Research right now?

1. **I <u>AM NOT</u>** thinking about participating in a research program to prevent breast cancer and ar not interested at this time.

2. **I <u>AM</u>** thinking about participating in a Medical Research program to prevent breast cancer and would like more information.

3. I already know about available breast cancer prevention research programs and **<u>I AM INTERESTED</u>** in joining a program.

4. I already know about available breast cancer prevention research programs and am **<u>NOT INTERESTED</u>** in joining a program.

5. **I AM ALREADY PARTICIPATING** in a breast cancer prevention research program. (If so, which program):

    a. Women's Health Initiative.

    b. Breast Cancer Prevention Trial (Tamoxifen).

    c. Other:_____

62. If you were thinking about participating in a breast cancer research program or are already participating, which program would/do you prefer? **(CIRCLE ALL THAT APPLY)**

    1. A program that would change <u>diet.</u>

    2. A program that involves taking a pill by mouth.

    3. Completing questionnaires and forms only.

    4. Other_____
    (Specify)

63. Have you ever participated in any type of Medical Research program?

NO _____ YES _____, If yes, type _____

<u>PLEASE GO TO NEXT PAGE</u>

PART VII

64. The following statements ask your thoughts and opinions about medical care you have received. **PLEASE CIRCLE ONE NUMBER ON EACH LINE:**

	No	Probably Not	Not Sure	Probably Yes	Yes
a) Doctors treat black women and white women the same.	1	2	3	4	5
b) Sometimes, if you are black in a white doctor's office, it is as if you do not belong there.	1	2	3	4	5
c) Racial discrimination in research is common.	1	2	3	4	5
d) In most hospitals, black women and white women get the same kind of care.	1	2	3	4	5
e) Doctors and nurses act the same way to white and black older women.	1	2	3	4	5
f) Blacks have the same opportunities as whites to participate in Medical Research.	1	2	3	4	5
g) If a black women and a white women were participating in the same research program they would be treated the same.	1	2	3	4	5
h) Black women can receive the care they want as equally as white women.	1	2	3	4	5
i) Black older women have fewer options to take part in research.	1	2	3	4	5

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Part VIII

The following statements ask your thoughts and opinions about your religious beliefs. **PLEASE CIRCLE ONE NUMBER WHICH BEST DESCRIBES YOUR RESPONSE.**

65. How religious would you say you are?

1. Not At All	2. Not Very Much	3. Somewhat	4. Pretty Much	5. Very Much

66. When you have decisions to make, in your everyday life, how often do you ask yourself what God would want you to do, or ask God for help in making the decision?

1. Never	2. Seldom	3. Sometimes	4. Often	5. Very Often

67. On the average, how often have you attended religious worship services (i.e., Sunday morning, evening, and/or other days) during the last year?

1. Never	2. A Few times a Year	3. Once or Twice a Month	4. Weekly or almost Weekly	5. More than Once a Week

68. To what extent are you conscious of some religious goal or purpose in life which serves to give direction to your life?

1. Not at all
2. To a small extent
3. To a moderate extent
4. To a large extent
5. To a very large extent

Thank you for your time. Your answers will be helpful for developing programs to help women prevent breast cancer.

Comments: _____

_____

_____

_____

Table 1
INSTRUMENTS

Summated Likert scales were used to measure all variables except Demographic Characteristics and Knowledge which included multiple choice and true or false formats.

Predictor Variables	**Scale**	**Mean**	**SD**	**Alpha**	**CVI**	**Score range**
Seriousness (Champion, 1993)	7	12.71	5.25	.71	-----	0 - 28
Susceptibility (Champion, 1993)	5	5.58	3.84	.83	-----	0 - 20
Health Motivation (Champion, 1993)	7	23.08	3.88	.72	-----	0 - 28
Knowledge	10	6.90	2.13	.62	1.00	0 - 40
Health Behavior	2	6.20	1.68	.18	1.00	0 - 08
Referents Influence	7	20.56	4.68	.64	1.00	0 - 28
Racism (Green, 1995)	9	13.93	8.08	.81	-----	0 - 36
Religiousness (Strayhorn, 1990)	4	16.41	3.34	.85	-----	4 - 20
Facilitating Factors	20	55.56	13.29	.86	1.00	0 - 80
Benefits	10	30.75	7.50	.85	1.00	0 - 40
Barriers	13	19.16	7.41	.80	1.00	0 - 52
Mediating Variables						
Positive Beliefs	9	19.38	6.59	.70	1.00	0 - 36
Negative Beliefs	15	26.13	11.95	.86	1.00	0 - 60
Behavioral Control	3	5.02	3.20	.50	1.00	0 - 12
Social Norm	1	1.02	1.48	-----	1.00	0 - 04
Attitudes	4	9.05	3.95	.50	.65	0 - 16
Outcome Variables						
Intention	2	2.85	2.82	.80	1.00	0 - 08
Research Participation	1	1.33	1.04	-----	1.00	0 - 03

Table 2. Respondent Characteristics

	AAW N=294
Age (mean years)	54.52
Range	25-79
Education (mean years)	13.86
Range	6-20
Marital Status	
Single/Never Married	10.5%
Married/Living Together	46.6%
Separated/Divorced/Widowed	42.9%
Household Income	
$\leq$ $10,999	21.7%
$11,000 - $30,999	34.3%
$31,000 - $50,000	25.3%
> $50,000	18.8%
Insurance Status	
No Insurance	10.9%
HMO	59.2%
Medical History	
Heart Disease	9.9%
Diabetes	13.9%
Hypertension	51.7%
Family History Breast Cancer	27.6%
Prior Research Participation	
Yes	12.3%
No	87.7%
Intention	
Want to Participate	
Yes	35.1%
No	24.4%
Not Sure	40.5%
Plan to Participate	
Yes	24.5%
No	30.7%
Not Sure	44.8%

	AAW
Stage of Research Participation	
Precontemplation	42.4%
Contemplation	47.6%
Preparation/Action	10.0%
Preferred Type of Research Participation	
Change Diet	79.9%
Take Pills by Mouth	25.4%
Complete Forms and Questionnaires	42.7%

Table 3

Predictors of Research Participation

Stepwise Multiple Regression				
Variables Selected	**Beta Weight**	**Multiple R^2**	**F**	**p**
Intention	.164	.2891	19.45	$<.01$
Negative Beliefs	-.180			
Social Norm	.179			
Insurance Status	-.133			
Benefits	.142			
Barriers	-.169			

Table 4

Predictors of Intention

Stepwise Multiple Regression				
Variables Selected	**Beta Weight**	**Multiple R^2**	**F**	**p**
Behavioral Control	.299	.3006	20.56	< .01
Negative Beliefs	-.111			
Positive Beliefs	.117			
Social Norm	.182			
Insurance Status	-.134			
Benefits	.127			

Table 5

Predictors of Positive Beliefs

Stepwise Multiple Regression

Variables Selected	Beta Weight	Multiple R^2	F	p
Fam. Hx. Breast Cancer	.125	.2973	15.07	< .01
Prior Research Participation	.104			
Knowledge	.117			
Health Motivation	.121			
Seriousness	.150			
Referent Influence	-.114			
Religion	.150			
Benefits	.372			

Table 6

Predictors of Negative Beliefs

Stepwise Multiple Regression				
Variables Selected	**Beta Weight**	**Multiple R^2**	**F**	**p**
Education	-.121	.3647	23.46	$<.01$
Marital Status	-.125			
Seriousness	.122			
Referent Influence	.135			
Racism	.179			
Benefits	-.179			
Barriers	.446			

Table 7

Predictors of Behavioral Control

Stepwise Multiple Regression				
Variables Selected	**Beta Weight**	**Multiple R^2**	**F**	**p**
Education	.142	.1193	7.80	< .01
Prior Research Participation	.119			
Seriousness	.152			
Benefits	.141			
Barriers	-.142			

Table 8

Predictors of Social Norm

Stepwise Multiple Regression				
Selected Variables	**Beta Weight**	**Multiple R^2**	**F**	**p**
Benefits	.175	.0307	9.25	< .01

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AFRICAN AMERICAN PERSPECTIVES ON RESEARCH PARTICIPATION: EMERGING THEMES.

Linda Lillington, RN, DNSc, Marta Ruvalcaba, BA, Rowan T. Chlebowski, MD, PhD, HARBOR-UCLA Medical Center, Torrance, California.

Nationally Funded Research trials aimed at breast cancer prevention in women at high risk are currently underway (Breast Cancer Prevention Trial, Women's Health Initiative). Recruitment of African American women for participation in these trials has been difficult. Without adequate representation, generalizability of findings to the African American population will be limited. Few studies have examined reasons for the lack of African American participation in clinical trials. The purpose of this study is to identify the attitudes and beliefs of African American women regarding breast cancer prevention research. The conceptual framework guiding the study is based on the Health Belief Model and Theory of Reasoned Action. Focus groups were used to explore beliefs and attitudes about breast health, breast cancer, breast cancer prevention, medical research, and ways to communicate information about research to the African American community. The groups were led by an experienced investigator using a standard focus group script. African American women without a diagnosis of breast cancer seen at the Breast Clinic of a large county hospital participated. Discussions were video and audio taped and transcribed. Eight focus groups were conducted (N = 45). Initial content analysis (Morgan 1988) of transcripts revealed emerging themes concerning participation in research: 1) importance of informed consent; 2) lack of understanding regarding the placebo concept which was viewed as "unfair" treatment; 3) distrust of the research process due to feelings of being experimented on, and being used as a guinea pig; 4) view of medical research as being important, as well as, a way to help others, to increase knowledge, and advance science if used properly; 5) view of financial compensation as important, providing funds to assist with transportation costs, and costs for child/elder care, rather than an incentive, as well as, a means of demonstrating consideration for participant's time and effort thereby promoting development of a "trusting relationship"; and 6) perception that research is for people who have the disease, not for healthy people, with participation possibly leading to development of the disease.

Although preliminary and involving a small group of respondents these results suggest important aspects of the African American view of medical research and provide direction for developing individualized and culturally relevant strategies to potentially enhance recruitment of African American women to breast cancer prevention trials. (Funded by State of California Breast Cancer Research Program).

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Signature of primary author Linda Lillington RN, DNSc

AFRICAN AMERICAN WOMEN'S PERSPECTIVES ON RESEARCH PARTICIPATION

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ABSTRACT

Nationally Funded Research trials aimed at breast cancer prevention in women at high risk are currently underway (Breast Cancer Prevention Trial, Women's Health Initiative). Recruitment of African American women for participation in these trials has been difficult. Without adequate representation, generalizability of findings to the African American population will be limited. Few studies have examined reasons for the lack of African American participation in clinical trials. The purpose of this study is to identify the attitudes and beliefs of African American women regarding breast cancer prevention research. The conceptual framework guiding the study is based on the Health Belief Model and Theory of Reasoned Action. Focus groups were used to explore beliefs and attitudes about breast health, breast cancer, breast cancer prevention, medical research, and ways to communicate information about research to the African American community. The groups were led by an experienced investigator using a standard focus group script. African American women without a diagnosis of breast cancer seen at the Breast Clinic of a large county hospital participated. Discussions were video and audio taped and transcribed. Eight focus groups were conducted (N = 45), initial content analysis (Morgan 1988) of transcripts revealed emerging themes concerning participation in research: 1) importance of informed consent; 2) lack of understanding regarding the placebo concept which was viewed as "unfair" treatment; 3) distrust of the research process due to feelings of being experimented on, and being used as a guinea pig; 4) view of medical research as being important, as well as, a way to help others, to increase knowledge, and advance science if used properly; 5) view of financial compensation as important, providing funds to assist with transportation costs, and costs of child/elder care, rather than an incentive, as well as, a means of

demonstrating consideration for participant's time and effort thereby promoting development of a "trusting relationship"; and 6) perception that research is for people who have the disease, not for healthy people, with participation possibly leading to development of the disease. Although preliminary and involving a small group of respondents these results suggest important aspects of the African American view of medical research and provide direction for developing individualized and culturally relevant strategies to potentially enhanced recruitment of African American women to breast cancer to potentially enhance recruitment of African American women to breast cancer prevention trials.

INTRODUCTION

Despite the recent advances in prevention, diagnosis, and treatment of cancer, unfavorable breast cancer rates have persisted in African American women and, are in fact, increasing (Bal, 1992). It has been suggested that the greatest potential for improving breast cancer outcome for African American women may be realized through aggressive implementation of prevention, diagnostic, and state of the art treatment programs and participation in cancer prevention trials (Millon-Underwood, 1993).

In 1990, the Office of Research on Women's Health was established with a mandate to strengthen and enhance prevention, diagnosis and treatment of illness in women and to enhance research related to diseases and conditions that affect women. Among the areas targeted for high priority research was cancer prevention, particularly breast cancer prevention, with a goal of including African American, Hispanic and poor women in research trials (Barry, Gooding, Harris, Hazzard & Winogard, 1993; Grisso and Watkins, 1992). It is well recognized that recruitment of adequate sample sizes of eligible subjects is critical to the success of any clinical trial (Bennett, 1993). Currently, there is a lack of participation by African American women in breast cancer research trials, particularly breast cancer prevention trials. Representation of African American women in these studies is important so that questions regarding breast cancer incidence and potential measures for breast cancer prevention can be addressed, and the safety and efficacy of new prevention measures for breast cancer can be evaluated. Strategies for recruitment of special populations must be based on an understanding of the factors that influence cancer incidence and mortality in the target population (Clark-Tasker, 1993).

The purpose of this study was to identify African American women's perceptions, attitudes and beliefs about breast cancer prevention, and willingness and intention to participate in breast cancer prevention research. Research questions addressed in this study include: 1) what are African American women's views about breast cancer and breast cancer prevention; 2) what are the perceptions, attitudes and beliefs of African American women regarding medical research; 3) what factors influence African American's women's decisions to participate in breast cancer prevention research; 4) what strategies do African American women recommend to increase research participation in the African American community?

BACKGROUND

Nationally funded research trials aimed at breast cancer prevention are currently underway. The NSABP Breast Cancer Prevention Trial is evaluating the effect of tamoxifen as breast cancer prevention in women at high risk; and the Women's Health Initiative is assessing as one component, the effect of dietary modification (low fat, high fruit, vegetable, and grain diet) on breast cancer prevention.

Recruitment of minority women to these trials has been difficult even when prospectively defined minority recruitment plans were required to be submitted with applications for funding. Without adequate representation, the manner in which preventive interventions will vary in their outcome across diverse populations will not be known, thus limiting the generalizability of study findings (Hansen, Collins, Malotte, et al, 1985).

Multiple factors are assumed to contribute to the lack of African American representation in clinical trials. One of the most important barriers is the Tuskeegee Syphilis Experiment which is a key factor in creating an atmosphere of distrust and suspicion, that

hampers cancer research efforts in many African American communities (Mc Cabe 1994). In an extensive review of the literature, Swanson and Ward (1995) identified multiple barriers to minority recruitment. These included sociocultural barriers, economic barriers, and individual barriers. Sociocultural barriers were identified as racial and ethnic discrimination and cultural beliefs concerning health seeking behavior. Many minority populations are fearful and distrustful of the medical care system as a result of health care professional's indifference and disrespect and feel devalued by the health care system. In addition, racial discrimination and segregation produce fear and mistrust of federally sponsored programs and clinical research.

The main economic barrier to participation by minority populations was lack of access to health care in general, with lack of health insurance particularly limiting access to health care and consequently clinical trials for low-income minority populations. Individual barriers were identified as perceptions and beliefs about health and disease and fatalistic attitudes specifically regarding cancer.

There are few studies which describe the attitudes of the general public toward medical research. Many published reports are either commentaries or descriptive presentations focusing on the roles of physicians, clinics and hospitals in recruitment. Description of participants rarely extends beyond demographic characteristics and exclusion criteria for subjects enrolled in the study (Swanson and Ward, 1995).

Millon-Underwood and colleagues (1993) reported findings from a descriptive survey of 220 African American men and women in the Midwest. Results indicated that the main factors influencing research participation were the perceived efficacy of the investigational program and misconceptions regarding opportunities for research participation limited only to

those with the disease. Lillington, Weintraub & Chlebowski (1994) reported results of a process evaluation examining African American women's reasons for refusal to participate in the Breast Cancer Prevention Trial. Results revealed a lack of belief in the susceptibility to breast cancer, concern about the impact of the study medication on current medical condition and therapy, unwillingness of women with breast cancer to share their diagnosis with family members, and concerns about side effects. Moody, Gregory, Baconegra, et al. (1995) recently reported African American women's reasons for refusal to participate in clinical trials: family pressure, child care responsibility, family duties, fear of the unknown, and decreased perception of vulnerability to disease with perceived good health.

The limitations of available reports, as well as, the paucity of research specifically addressing factors influencing African American women's decisions to participate in breast cancer prevention trials support the need for further research in this area. Understanding the factors influencing decisions to participate in medical research will be useful for developing targeted strategies to promote cancer prevention research participation among African American women.

METHODS

Setting and Sample

The potential population of subjects for this study was comprised of African American women who attended the Outpatient Breast Clinic at a large university affiliated County Hospital in Southern California. African American women represent over 1/3 of the women receiving care at the Breast Clinic. These women are generally economically disadvantaged, and do not have medical insurance. The majority do not have breast cancer and are seen for

breast health maintenance. Eligibility criteria included: age greater than or equal to 35 years, African American ethnic background, and no personal history of breast cancer.

After review of the Breast Clinic list of registered patients over the past three years, 800 potential subjects were identified. Letters of invitation were sent to 200 randomly selected African American women identified from the listing. The letter of invitation explained the purpose of the study, study requirements, i.e., the group discussion and topic area, $20 honorarium, and instructions for contacting the investigator's office if interested in participating in the study. Potential participants were also invited to bring a friend who also met eligibility criteria. Eligibility was verified by telephone and participants were scheduled to attend a focus group session.

Of the 200 mailed invitations, 27 were not delivered due to an incorrect address. A total of 57 women expressed interest (30.6% response rate, 57/173). Forty-five women attended the focus group sessions, including seven participants resulting from the "Bring a Friend" invitation. A total of 19 women were ineligible due to a diagnosis of breast cancer (17%), work schedule (25%), dependent care (16%), transportation problems (17%) and inability to contact after initial interest expressed (25%). Focus groups were scheduled on the same day as Breast Clinic to accommodate participant's schedules. Participants in the focus groups received an honorarium of $20 as compensation for their time. Refreshments were also available during the group discussions.

Procedures

Data was collected using a focus group format. Focus groups were structured to stimulate in depth discussion from the participant's perspective concerning perceptions,

beliefs, and attitudes about breast cancer and participation in medical research. The conceptual framework guiding the study was based on the Health Belief Model and Theory of Reasoned Action organized according to the PRECEDE Health Education Planning Framework particularly exploring predisposing, enabling, and reinforcing factors potentially influencing research participation behavior (Glanz, Lewis, Rimer (Eds.) 1990; Green, Krueter, Deeds, Partridge, 1980) (Figure 1). Discussions explored beliefs and attitudes about breast health, breast cancer, breast cancer prevention, medical research and ways to communicate information about research to the African American community.

Prior to initiation the study was reviewed and approved by the Institutional Review Board for Protection of Human Subjects. After consent, subjects participated in the focus group discussion and completed a brief self-report questionnaire regarding demographic characteristics. Eight focus groups consisting of 3 to 7 persons each were held between June, 1994 and October, 1994. The focus groups were facilitated by the investigator, experienced in focus group techniques, and an African American research nurse familiar with breast cancer issues in the African American community. All group discussions were audio taped and video taped to aid in data analysis and lasted 1 1/2 to 2 hours.

Sessions began with an explanation of the informed consent, purpose of audio and video taping, and goals for the group. Divergence of opinion was encouraged and all participants were asked to offer their opinion as it was explained that there were no right or wrong answers. The facilitators adopted a stance of curiosity and incomplete understanding and used a focus group script involving a number of open ended questions. The script consisted of core questions with subsequent probes. Script questions were reviewed by a

judge panel of three experts and tested in a pilot focus group involving support staff from the Breast Clinic, many of whom were representative of the African American participants, to determine feasibility of the approach and appropriateness of the script. Questions posed to participants included: 1) What do you do to try and stay healthy? 2) What comes to your mind when you think about breast cancer? 3) What comes to your mind when you think about preventing breast cancer? 4) What do people think about medical research? 5) When you think about participating in research about preventing breast cancer what thoughts come to your mind? 6) If we wanted to increase people's interest in participating in research what would we need to do in your community?

Data Analysis

A content analysis of the group discussions was undertaken using procedures outlined by Morgan (1988) and Krueger (1988). The audio tapes of the discussions were transcribed verbatim, reviewed for accuracy and completeness, and corrected prior to content analysis. The typed transcript was marked, cut apart, and sorted according to relevance to specific discussion questions. Responses were coded independently by the investigator and African American research nurse. The organized comments of the participants were assessed and grouped according to themes expressed in the comments themselves. Comments that were mentioned by more than one individual were identified and it was noted when individuals shared a common opinion, belief or practice. Independent reports were compared, consensus was reached and summary statements were prepared. Additionally, 19 of the original 45 focus group participants returned to a group discussion to verify and validate findings by reviewing a summary of the results.

RESULTS

Sample Characteristics

Forty-five African American women participated in the focus group discussions. The demographic characteristics of focus group participants are shown in Table 1. The average age of the women was 51 years (range 35-91 years). Over half of the women completed a high school education with many of the women going on to complete some college or specialized training after high school (44.5%). Most of the women were either retired (22.2%) or not employed (31.1%). The majority of women (60%) reported an income level $\leq$ $10,000, and many (48.8%) had Medicare or Medical insurance coverage. Only a few women (6.7%) reported prior research participation and less than 20% of participants reported a family history of breast cancer.

In general participants had a great need to share personal experiences related to their own breast health (mammography, having a breast lump or having a biopsy), and experiences of family members and friends who have had breast cancer. The major findings from the discussions were categorized so as to specifically identify Predisposing, Reinforcing and Enabling Factors potentially influencing African American women's decisions to participate in medical research.

Beliefs about Breast Cancer

When asked to share thoughts about breast cancer, most women reported that breast cancer caused fear, particularly fear of death, fear of losing a breast and the impact this might have on one's partner, fear of radiation and treatment side effects, and fear of pain. Most women associated breast cancer with a fatal outcome, and shared their personal experiences

with friends or relatives who had breast cancer and had died. A few participants did recognize the importance of early detection as a means of reversing the perceived fatal outcome due to breast cancer.

> "...I know we always associate it (breast cancer) with death but that isn't the case all the time."

> "...if you can catch it in time, it's preventable..a lot of ladies don't think this way..."

Perceived lack of susceptibility and denial were commonly expressed. Some women did not feel they were at risk for developing breast cancer and many felt that it was outside of their control, i.e "... it's in God's hands." Many participants also felt that women would not want to know if they had breast cancer because they would feel doomed.

> "...Woman are in denial... they think it's not going to happen to me...they do not get medical care when they have breast problems...they don't want to know."

Perceptions About Breast Cancer Prevention

Discussion concerning breast cancer prevention was initially limited since women felt that in order to prevent breast cancer, a cause must be known. Thoughts about causes of breast cancer included chemical preservatives in food, pesticides, heredity, virus, and breast feeding. Although food was identified as a potential cause, the concept that diet, particularly a low fat diet, might prevent development of breast cancer was not addressed.

Knowledge of risk factors was limited to family history. Some women felt, however, that because they had other health problems, breast cancer would not "get them."

> "...I just don't think it's gonna hit me...I just don't accept it's gonna hit me."

Others reported that it was not always easy to find out about one's family history since the older generation doesn't talk about cancer.

> "...what gets me is the denial because if they [older generation] won't talk about it and tell the next generation...you don't know anything."

Most women identified screening measures such as mammograms, self-exam and regular check-ups, as well as, knowing one's family history, and prayer as ways to prevent breast cancer suggesting a lack of understanding regarding primary and secondary prevention concepts.

Thoughts about Medical Research

In general, most participants felt the general public was not aware of research, "People don't think about research...they don't know about it." Common positive perceptions about research included a sense of altruism: increase knowledge, save lives, help others, as well as, a way to help oneself.

> "...We found out a lot on account of doing research to better treat diseases..."

> "...I think it's good, if it helps people..."

A general fear of research was also reported due to a lack of understanding about the research process and procedures that are involved, and the thought of being used as a "guinea pig," often referring to the Tuskeegee study.

> "...If I knew more about it, I wouldn't feel afraid of it [research]...ignorance makes you afraid..."

> "...it makes me sad that they experiment with people...like being a guinea pig...they always do that with older people."

"...it [fear] all comes from the research in the South, on the Black men, the Mississippi thing (Tuskeegee study)..."

Concerns about side effects and problems that may occur in the future were also expressed, as was fear of "getting the disease" by participating in the research.

Perceptions about the Prevention Research

Responses varied in regard to the preferred type of prevention research i.e., diet versus pill. Some women stated they would prefer taking a pill because it was perceived to be "easier" and others stated they would prefer diet because of the "natural" approach.

"I don't want to do the research where you want me to take something [pill]..."

Others reported that they would prefer research in which something (blood, tissue) was taken from them as opposed to taking a medication.

"I feel better if you were taking something from me than to put something in my body."

Sources of Distrust in Medical Research

The issues of distrust and suspicion in medical research were raised by many participants specifically related to: government sponsored research (Tuskeegee study, government control of medical care), use of placebos which was felt to be "denying people treatment", and skepticism about procedures to be done, and whether subjects would be told the truth.

"Research is fine if people know what's going on...if they [government] do it behind their back and they don't know it's going on...and something happens...that's wrong."

"Research is political...people [are] just getting rich off cancer research..."

"...if you find out you didn't get the medicine [placebo] you feel used..."

"How do we know research is being used properly..how do we know we're being told the truth..."

Building trust and gaining confidence were considered important determinants for research participation.

"...build the trust between the people and the researcher..., get their confidence so that they will know they [are] not going to be hurt."

"Give us the truth but give it in a way that we can receive it and understand it."

Many women also emphasized the importance of follow through and informing participants of the results of the research as a means of building trust and confidence

Importance of Informed Consent

There was a general consensus that informed consent was the key determinant for research participation. This was operationalized as knowing exactly what procedures would be done, where and how they would be done, the risks and benefits, side effects and sharing of results.

"Research is OK, just as long as you know what you're getting into."

"I want to know before hand so I can decide if I want to get into it or not."

"...just make sure that whatever you tell them is exactly what you're gonna really be doing...in the older [$\geq$50 years] age group, there is nothing worse than misleading."

Who Participates in Research?

A variety of opinions were voiced regarding who should participate in research. A few women felt it was everyone's responsibility.

"All people should participate...it's our responsibility..."

One participant felt that people would be more open to participating in research concerning health problems that are in the African American culture:

> "...people would be more apt to participate in something if they know what it is...a certain disease that's been in their community, it's what affects that culture."

In contrast, a few women raised the question "why study me..why am I so different" suggesting they did not want to be singled out.

Some women felt people with a disease or illness who had nothing else left to try or people at high risk for developing the disease should participate in research. Participation in research by healthy people was not generally recognized since "...people are here and now...they are not worrying about the future."

Barriers to Research Participation

Discussion regarding barriers to research participation often led to sharing of experiences related to receiving health care in a "county" system. Many women expressed a lack of confidence in the county health care system related to long wait times, impersonal treatment, and lack of follow-up:

> "...when I come to the county hospital, I don't have any trust ...with private doctors I have trust.. you can sit and talk confidential, there's respect."

A few women shared "good" experiences in receiving health care in the county system and reported that "...if you know how the system works you can get the same treatment as a person with medical insurance."

Other barriers to research participation included time, lack of awareness, lack of interest, cost, responsibilities at home, fear, distrust and suspicion.

Recommended Recruitment Strategies

Women identified compensation as an important recruitment strategy either in cash, a "free" health exam or a free mammogram.

> "..it's important as a consideration for what the person is doing, the gas, the time, bus fare is sky high..."
> "...[people] don't have money to come out."
>
> "...the person is taking their time, effort, energy...it's a nice thank you."
>
> "..if some [research programs] have a free mammogram or a free check-up...that makes a lot of difference..."

Most women felt a personal approach, using a personalized letter inviting individuals to participate in a "study" or "program" was most effective. They cautioned about using the word "research" since it generates a fear response. Participants also recommended that talking with people in the program, would be helpful.

> "...give them an example of somebody that [has] been through it..."

Many women also felt that the program needed to be offered in the community, run by people with whom they feel comfortable:

> "you can't just send anybody, it would have to be someone they could be comfortable with...someone to talk to them in a way they [can] understand."

Recommendations for increasing awareness included posting flyers and pamphlets in "places where they're really tuned in...most black people, especially for women, they go to church." The media (TV, newspapers, radio) was also identified as an important source of providing information to the community as was word of mouth. The importance of going to the local community was emphasized:

"Go to the community because every household is different...some don't read, don't watch TV..."

DISCUSSION

The results of the content analysis suggest that African American women have some unique views about prevention and participation in medical research which have implications for developing tailored recruitment strategies. A model for recruitment, derived from focus group findings, identifies specific Predisposing, Enabling, and Reinforcing Factors which need to be considered in planning recruitment strategies for breast cancer prevention trials in the African American community. These have been summarized in Tables 2-4.

Predisposing Factors

Specific Predisposing Factors are summarized in Table 2. These include knowledge deficits regarding: ongoing breast cancer studies, the concept of prevention, breast cancer risk factors, and the research process including common terminology. Although research was generally felt to be important and necessary, it was not a topic that was commonly discussed.

Providing information regarding the impact of breast cancer was felt to be important to increase understanding of the magnitude of the problem within the African American community. The women in this study tended to perceive breast cancer as a serious illness, causing a great deal of fear. Denial and an underestimation of personal vulnerability were also identified as important potential barriers to seeking health care, as well as, research participation. Knowledge deficits, denial and perceived lack of susceptibility have been previously recognized as barriers to research participation. (Mack, McGrath, Pendleton, Zieber, 1993).

A fatalistic attitude towards breast cancer outcome was also apparent, as has been previously identified in the African American population (Bloom, Hayes, Saunders, & Flatt, 1987; Underwood, 1992). It is interesting that factors associated with fatalistic beliefs about cancer outcome, i.e., lack of cancer knowledge, limited access to health care, fear of being used as a "guinea pig," have also been identified as important determinants of research participation (Dula 1994; Guillory, 1987). Powe (1995) recently speculated that the development of fatalistic perceptions towards cancer may be related to an individual's actual experiences with cancer among their family members and friends. This was apparent from the focus group discussions. Many African Americans have witnessed the repeated cycle of late cancer diagnosis and death and, therefore, may have more fatalistic beliefs. They may be less apt to participate in preventive health behaviors or be motivated to participate in prevention related research because it is perceived to not matter.

Ethical issues related to research participation emphasized the importance of informed consent. Participants felt it was necessary to know exactly what would be required in the research, particularly, what would be done, how long it would take, the side effects, risks and benefits. This information was considered necessary in order to be able to make a decision about study participation. Research was thought to be important and necessary for increasing knowledge and advancing science, "if used properly", suggesting participants were not certain about whether it was right or wrong. Research on animals was perceived to be acceptable but research using humans was less certain. This finding may be the result of the extensive knowledge of the Tuskeegee Syphilis Experiment which has generated wide spread suspicion and distrust among the African American community regarding medical research (Freeman,

1993).

The research process was also not well understood. Randomization and use of a placebo were viewed as "unfair" and "denying people treatment." These concepts need to be explained using concrete examples and simplistic language in order for individuals to understand the rationale for these procedures in applicable studies.

Another interesting finding was the perception that research was for people who had the disease or people at high risk rather than for healthy people. This has been previously reported by Millon-Underwood, et al, (1993) and has definite implications for prevention trial research participation. A possible explanation has been that health care is generally important only in the presence of symptoms, with prevention measures receiving low priority (Bloomenthal, 1995). Although participants in the focus group discussions were well aware of healthy behaviors, many did not practice these behaviors. It was interesting that the knowledge of healthy lifestyle behaviors did not seem to translate into the concept of prevention. In fact, in the initial focus group, the first focus group question asked, "What do you do to try and prevent disease?" Responses were limited, the concept of prevention was not well understood. Subsequently, participants were asked, "What do you do to try and stay healthy?" which generated more fruitful discussion.

Reinforcing Factors

Findings from this study identified positive, as well as, negative reinforcing factors potentially influencing research participation (Table 3). Important referents were identified as family members and physicians, as well as, persons who are participating in the program. Gaining local community endorsement, and physician support were considered important for

enhancing acceptance of research participation.

The influence of religious beliefs on health and illness was strong. Religious beliefs may operate as a mechanism influencing a perceived external locus of control over health, i.e., health is in God's hands, with prayer being identified as a mediating mechanism to influence health or disease outcomes. This may impact acceptance of preventive health behavior and participation in prevention research negatively if individuals do not perceive control over their own health (Jackson, 1991).

The fact that research may be sponsored by federal government agencies was not necessarily perceived in a positive light. The climate of racial discrimination and segregation in our society has resulted in fear and mistrust of federally sponsored projects, clinical research and academic medicine (Nickens, 1990; Thomas, Pinto, Roach, and Vaughn, 1994).

Enabling Factors

Enabling factors which may potentially facilitate or inhibit research participation behavior are summarized in Table 4. Access to ongoing research was limited due to lack of awareness of ongoing breast cancer prevention trials, i.e., the NSABP Breast Cancer Prevention Trial and the Women's Health Initiative, as well as, limited availability of programs in the local community. Participants were also unsure about where they could go to get information regarding research programs. This suggests that there has been little publicity regarding these trials in the African American community.

Reimbursement for research participation was viewed as an important facilitating factor. Participants did not necessarily view cash payment or even "free" health evaluations as incentives, rather they viewed these activities as means for enabling participants to complete

required study activities which may otherwise be unaffordable due to costs for procedures, lack of transportation, lost wages and costs for child care. Unique to this study was the finding that reimbursement was viewed as recognition for participant's time, effort, and energy resulting in a feeling of being valued for participating in the program. Reimbursement was felt to be a means for building trust and confidence, and hence a way to possibly reduce the current widespread suspicion and mistrust felt in the African American community related to research participation. Incentives such as transportation, child care, and cash payments have been used in research studies involving minority populations in the past (Moody et al. 1995; McCabe et al. 1994; Murdaugh 1990). The sole impact of the use of reimbursement as a recruitment strategy in minority populations, however, has not been reported.

Participants also emphasized the importance of following through and notifying subjects about the results. As was demonstrated in this study, 47% of the participants returned to the validation discussion session almost two years after the study began because they were interested in the outcome.

The use of a personalized approach was also recommended, e.g., personalized letters of invitation and individual doctor recommendations. This combined with follow through and reimbursement may lead to building trust and confidence resulting in increased African American participation in breast cancer prevention research.

Barriers identified were similar to those reported in the literature including concerns about side effects, fear of the unknown, poor quality of care (impersonal approach, long waits), distrust, transportation problems, costs, and time (Swanson and Ward, 1995).

In summary, based on these findings, recruitment strategies targeting African American

women for breast cancer prevention research participation need to include activities and approaches to increase awareness, alter misconceptions, reduce barriers and maximize facilitating factors.

Limitations

Findings from this study are considered preliminary and are not generalizable beyond the African American women who participated in the focus group discussions. Because focus groups involve small numbers of individuals, sampling techniques are often not scientific and open to selection bias. It will be important to extend the research using quantitative approaches, conducting studies which include women who are more representative of the African American population in terms of education, income and age range appropriate for the target research.

CONCLUSION

Findings from the focus group discussions provide insight into the perceptions, attitudes and beliefs of African American Women regarding breast cancer, breast cancer prevention, research participation and strategies to enhance recruitment of African American women to breast cancer prevention research trials. Although research was generally thought to be important and effective, skepticism and suspicion were expressed when individual participation was discussed. Important factors promoting research participation by African American women centered on establishing credibility at the local level (community leader, organization, and physician endorsement), developing trust and building confidence (ethnic matched personnel, talking with people in the program, personalized recruitment approaches); assuring informed consent; increasing access and availability (take the program to the

community, publicize the program); overcoming barriers (cost, transportation, time, offering dependent care); developing communication messages using an altruistic appeal; offering "free" mammograms and health evaluations; and providing financial compensation for individual time and effort required to complete study activities (Figure 2).

While these are preliminary findings in need of further exploration in larger groups of African American women, they do provide direction for the development of culturally relevant strategies to enhance recruitment of African American women to breast cancer prevention trials. Nurses increasingly are in positions to participate in planning, developing and implementing recruitment strategies to achieve successful accrual of eligible participants to ongoing clinical trials. Incorporation of techniques and approaches tailored to the needs of special populations may generate increased recruitment yields and permit generalizability of study findings to women of all ethnic backgrounds and socioeconomic strata.

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Table 1 - Demographic Characteristics of Focus Group Participants

N = 45

	No	%
Education		
Less than High School	9	20.0
High School	16	35.5
College	20	44.5
Mean Age (years)	51 (range 35 - 91)	
Martial Status		
Single/Never Married	9	20.0
Married/Living together	10	22.2
Separated/Divorced	19	42.2
Widowed	7	15.6
Employment		
Full Time	8	17.8
Part Time	8	17.8
Not Employed	14	31.1
Retired	10	22.2
Other	5	11.1
Income		
$\leq$ $10,000	27	60.0
> $10,000 $\leq$ $20,000	12	26.6
> $20,000	6	13.3
Health Insurance		
Medicare/Medical	22	48.4
Private Insurance	8	17.8
No insurance	15	33.4
Family History of Breast Cancer		
Yes	8	17.8
No	37	82.2
Prior Research Participation		
Yes	3	6.7
No	42	93.3

Table 2. Predisposing Factors

Knowledge Deficits:

- Ongoing Research
- Breast Cancer Risk Factors
- Breast Cancer Incidence
- Concept of Prevention
- Research Process/Terminology

Attitudes and Beliefs:

- Fear
- Breast Cancer Susceptibility
- Denial
- Fatalism

Ethics of Research

- Right vs Wrong
- Informed Consent:
    - Procedures
    - Risks/Benefits
    - Side Effects
- Randomization/Placebo
- Racism
- Who Participates

Table 3 Reinforcing Factors

- Referents
  - Family
  - Physician
  - People in Program
- Community Leader, Organization Endorsement
- Religiousness
  - External Locus of Control
- Government Sponsored Research
- Social Desirability

Table 4 Enabling Factors

Facilitating Factors:

- Availability of Research
- Access to Research
- Compensation
- Trust/Confidence:
    - Personalized Approaches
    - Follow Through
- Benefits

Barriers:

- Side Effects
- Risks
- Time
- Cost:
    - Transportation
    - Lost Wages
    - No Insurance
    - Dependent Care
- Perceived Poor Quality of Care
- Fear of Unknown
- Distrust

BREAST CANCER RESEARCH PARTICIPATION: SIMILARITIES AND DIFFERENCES IN AFRICAN AMERICAN AND CAUCASIAN WOMEN'S VIEWS

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The greatest potential for reducing breast cancer (BC) mortality may be realized through aggressive implementation of breast cancer prevention research (BCPR) such as the ongoing Women's Health Initiative, and NSABP Breast Cancer Prevention Trials. Successful completion of these important clinical trials is contingent on the participation of adequate numbers of subjects. Recruitment of African American women (AAW) is of particular concern given the disproportionate mortality and morbidity due to breast cancer. The purpose of this research was to systematically examine the similarities and differences between AAW's and Caucasian women's (CW) views about BC and research participation as a means of developing successful recruitment strategies. The conceptual framework was based on the Health Belief Model (HBM), Theory of Reasoned Action (TRA), and Transtheoretical Model. A 69-item survey questionnaire, developed based on focus group findings, was tested for validity (CVI = .98) and reliability (Cronbach Alpha = .71). This was mailed to 10,000 women in the Los Angeles area in Spring, 1996 with oversampling of AAW. Items explored HBM variables (susceptibility, seriousness, health motivation, benefits, barriers, knowledge), TRA variables (social norm, positive and negative beliefs about research, behavioral control, and referent influence), and stage of research participation behavior (RPB). A total of 512 women responded (5.2%). Results reported involve responses (N=448) from AAW (65.6%) and CW (34.4%) only. Respondents' mean age was 56 yrs., 91% had $\geq$ 12 yrs. education, 47.3% were married, 89.7% had health insurance, 31.9% had a family history of BC, and 10.9 % reported prior research participation. Stage of research participation behavior varied from "never thought about it/not interested" (48.1%), "thinking about it" (42.6%), and "interested or already participating" (9.3%). Pairwise t-tests with post hoc Bonferroni tests were used to examine response differences between AAW and CW. Significant differences were identified for: knowledge ($t = -4.15$, $p < .001$), susceptibility ($t = 1.97$, $p < .05$), benefits ($t = 3.38$, $p < .001$), barriers ($t = 2.02$, $p < .05$), referent influence ($t = 3.58$, $p < .001$), attitudes ($t = -2.90$, $p < .01$), and negative beliefs ($t = 2.07$, $p < .05$). AAW perceived less susceptibility to BC, greater benefits and barriers to research participation, had lower knowledge scores, perceived less positive attitudes and greater negative beliefs about research, and stronger referent influence compared to CW. Using stepwise multiple regression techniques, significant predictors, explaining 30% of the variability in AAW's RPB, included: barriers, negative beliefs, benefits, social norm, not having health insurance, and intention. For CW, significant predictors, explaining 36% of the variability in RPB, included: positive beliefs, seriousness, intention, prior research participation, and age. These findings identify similarities and differences in AAW's and CW's views about BC and RPB which present possibilities for tailoring recruitment strategies to increase research participation addressing the particular needs and concerns of AAW and CW.

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BELIEFS ABOUT RESEARCH AND STAGE OF RESEARCH PARTICIPATION BEHAVIOR

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Recruitment to Breast Cancer Prevention Trials (BCPT) including the Women's Health Initiative Trial is ongoing. Successful completion of such large multicenter clinical trials depends on participation of adequate numbers of subjects. Little published data is available providing guidance for development of successful recruitment strategies to achieve target accrual. The purpose of this study was to examine the differences in Health Belief Model (HBM) and Theory of Reasoned Action (TRA) variables by stage of research participation behavior (RPB). A 69-item survey questionnaire, developed based on focus group findings, tested for reliability (Cronbach alpha = .71) and validity (CVI = .98 by expert judge panel review), was mailed to 10,000 women in the Los Angeles area in Spring, 1996 with oversampling of African American women (AAW). Items explored HBM variables (susceptibility, seriousness, health motivation, benefits, barriers, and knowledge) and TRA variables (attitudes, social norm, positive and negative beliefs about research, behavioral control, and referent influence) and stage of RPB. A total of 512 women (5.2%) responded. Results reported include responses (N=448) from AAW (65.6%) and Caucasian women (34.4%) only. The mean age was 56 years and mean educational level was 13.76 years. Family history of breast cancer was reported by 31.7% and 10.9% reported prior research participation. Women were staged for RPB using three stages: 1) precontemplation (48.1%) - never thought about research participation/not interested; 2) contemplation (42.6%) - thinking about research participation and want more information; 3) preparation/action (9.3%) - already know about breast cancer prevention research and are interested or already participating. One way analysis of variance with post hoc Bonferroni tests were used to identify differences in HBM and TRA variables by stage of RPB. Results indicated significant differences between women in precontemplation and preparation/action and between women in preparation and contemplation for attitudes ($F = 12.33$, $p < .0000$), benefits ($F = 16.45$, $p < .0000$), barriers ($F = 27.88$, $P < .0000$), positive beliefs ($F = 17.02$, $p < .0000$), and negative beliefs ($F = 28.64$, $p < .0000$). Significant differences between women in precontemplation and preparation/action and between women in contemplation and preparation/action were realized for behavioral control ($F = 23.91$, $p < .0000$), intention ($F = 42.66$, $p < .0000$), and social norm ($F = 20.30$, $p < .0000$). Knowledge evidenced a significant difference between women in precontemplation and contemplation ($F = 4.42$, $p < .05$). Attitudes about medical research, benefits, barriers, positive and negative beliefs about research participation and knowledge may be important for targeting women in the precontemplation stage, while perceptions about behavioral control, social norms and identification of factors influencing intention would be important for women in the precontemplation and contemplation stages. These findings suggest important possibilities for recruitment strategies tailored to specific stage of RPB which may enhance accrual, retention and adherence to BCPT.

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ATTITUDES AND ADHERENCE OF AFRICAN AMERICAN WOMEN TO DIETARY FAT INTAKE REDUCTION. **L Lillington, M Grosvenor, I Johnson, RT Chlebowski, Harbor-UCLA Medical Center, Torrance, CA 90509**

Current NCI guidelines call for reduction in dietary fat intake for the general population. In this regard, conventional dietary change programs may not be suited to the cultural needs of African American Women (AAW). To begin the process of developing appropriate intervention strategies, parallel quantitative and qualitative methods were used. First, dietary change was examined in a subset of AAW participating at Harbor-UCLA in the multi-center Women's Intervention Nutrition Study (WINS) which randomized postmenopausal patients with resected breast cancer to Dietary Control or Intervention, designed to reduce fat intake to 20% of calories using an intensive, one-on-one approach (JCO 11:2072). In addition, a series of four focus groups were conducted to identify enabling factors and barriers impacting dietary change among a convenience sample of 22 AAW without breast cancer. Dietary outcome for the WINS trial participants ($N=21$) indicated that a significant ($p<0.01$) reduction in dietary fat intake was achieved in the Dietary Intervention Group in terms of: fat gram intake/day (52 ± 5 v 28 ± 4 g), % calories from fat (35 ± 2 v 20 ± 2 %), and body weight (80.8 ± 3.9 v 79.3 ± 3.2 kg) with all values, mean $\pm$SEM at entry v 3 mos, respectively. The magnitude of change was closely comparable to that reported for the overall 290 patient population.

Focus group discussion questions based on the Theory of Reasoned Action and Health Belief Model explored cognitive, social and environmental factors facilitating or inhibiting adoption of and adherence to dietary change behavior. AAW without breast cancer participating in the focus groups identified enabling factors for dietary change which included providing information on: "healthy" food choices and preparation (recipes), substitute seasonings to replace traditional "soul food" choices; education through community based sources (schools, churches etc.); as well as health professional recommendations. Barriers to dietary change included: a lack of focus on preventive health behavior; expectations of traditional high fat foods by family; church and social events (often serving traditional foods); and perception of increased time and cost required for a low-fat eating plan. These findings suggest that dietary change is achievable in a highly motivated population of AAW with breast cancer using an intensive dietary intervention. Extension of this success to the general population of AAW may be facilitated by attention to culturally relevant enabling factors and barriers.

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Factors Influencing African American Women's Decisions to Participate in Breast Cancer Prevention Research, Lillington, Linda M, DNSc, Sayre, James W, PhD, Chlebowski, Rowan T, MD, PhD; Harbor-UCLA Research and Education Institute, Torrance, California.

Recruitment of African American Women (AAW) to ongoing breast cancer prevention research (BCPR) trials has been difficult. Few studies have explored reasons for lack of participation. The purpose of this study was to systematically examine factors influencing decisions to participate in research. The conceptual framework was based on the Health Belief Model and Theory of Reasoned Action. A 69-item survey questionnaire, developed based on focus group findings , was tested for validity and reliability. This was mailed to 6,000 AAW in the Los Angeles area during Spring 1996. Items explored beliefs and attitudes about breast cancer, medical research, preferred type of prevention behavior, and interest in research participation (RP). A total of 311 AAW responded (5.2%). The mean age was 54 yrs., 91% had $\geq$ 12 yrs. education, 46% were married, 89% had health insurance and 28% reported a family history of breast cancer. Research participation (RP), measured as a stage of behavior change, varied from "never thought about it/not interested" (42.4%), "thinking about it" (47.6%), "interested" (8.8%), and "already participating" (1.2%). Significant predictors, explaining 29% of the variability in RP, included: negative beliefs about research (NB) (concerns about side effects, use of placebos, distrust, fear of experimentation), intention to participate, health insurance status, social influences (physician and family encouragement), benefits of RP, and barriers to RP. Positive beliefs about research (important for one's health, find better treatment, altruism) exerted an indirect effect on RP via intention. These findings suggest strategies aimed at reversing NB (e.g. building trust, assuring informed consent), gaining support of important referents, eliminating barriers (e.g. assisting with transportation, offering convenient hours), promoting the benefits of RP, and obtaining endorsement of BCPR programs by insurance carriers may enhance AAW's participation.

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